Exhibits 1 – 8

TO THE DECLARATION OF AMY WALSH RE: DEFENDANT RAMESH BALWANI'S MOTION TO EXCLUDE EVIDENCE AND ARGUMENT THAT PHARMACEUTICAL REPORTS WERE ALTERED

Exhibit 1

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA,	)	CR-18-00258-EJD
PLAINTIFF,	)	SAN JOSE, CALIFORNIA
VS.	)	VOLUME 4
ELIZABETH A. HOLMES,	)	SEPTEMBER 8, 2021
DEFENDANT.	)	PAGES 492 - 646

TRANSCRIPT OF TRIAL PROCEEDINGS
BEFORE THE HONORABLE EDWARD J. DAVILA
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

FOR THE PLAINTIFF:
UNITED STATES ATTORNEY'S OFFICE
BY: JOHN C. BOSTIC
JEFFREY B. SCHENK
150 ALMADEN BOULEVARD, SUITE 900
SAN JOSE, CALIFORNIA 95113

BY: ROBERT S. LEACH
KELLY VOLKAR
1301 CLAY STREET, SUITE 340S
OAKLAND, CALIFORNIA 94612

(APPEARANCES CONTINUED ON THE NEXT PAGE.)

OFFICIAL COURT REPORTERS:
IRENE L. RODRIGUEZ, CSR, RMR, CRR
CERTIFICATE NUMBER 8074
LEE-ANNE SHORTRIDGE, CSR, CRR
CERTIFICATE NUMBER 9595

PROCEEDINGS RECORDED BY MECHANICAL STENOGRAPHY
TRANSCRIPT PRODUCED WITH COMPUTER

CONTRACT WITH THE U.S. ARMY BURN CENTER IN TEXAS FOR A RESEARCH STUDY IN THE UNITED STATES THAT WAS SUFFERING FROM LOW PATIENT ENROLLMENT.

AFTER THAT, THE DEFENDANT WAS ALSO TRYING TO USE HER CONTACTS, INCLUDING CONTACTS ON HER BOARD, TO GET DIFFERENT BRANCHES OF THE MILITARY TO USE THE MINIATURE BLOOD ANALYZER.

BUT THE DEFENDANT'S EFFORTS NEVER WENT ANYWHERE AS YOU WILL HEAR FROM A THERANOS INSIDER AND FROM OTHERS.

THE DEFENDANT, HOWEVER, LED INVESTORS TO BELIEVE THAT THE MINIATURE BLOOD ANALYZER HAD BEEN DEPLOYED IN REMOTE AREAS OF THE WORLD; THAT IT WAS USED ON MILITARY HELICOPTERS, OR MEDIVACS, AND THAT IT WAS ACTUALLY SAVING THE LIVES OF SOLDIERS IN THE FIELD.

THE THIRD CATEGORY OF MISREPRESENTATION THAT YOU WILL HEAR ABOUT IS THAT THE DEFENDANT MISLED INVESTORS INTO BELIEVING THAT PHARMACEUTICAL COMPANIES ENDORSED AND APPROVED THE MINIATURE BLOOD ANALYZER. AND LET ME GIVE YOU ONE EXAMPLE OF HOW THE DEFENDANT DID THAT.

AS I MENTIONED EARLY ON, THERANOS DID DO SOME WORK WITH PHARMACEUTICAL COMPANIES. ONE OF THEM WAS PFIZER. SOME OF YOU MAY HAVE HEARD OF PFIZER, AND WE'RE ALL GRATEFUL TO PFIZER FOR THE ABILITY TO BE HERE TODAY.

PRIOR TO 2009, PFIZER HAD A $900,000 CONTRACT WITH THERANOS.

IN OCTOBER OF 2008, THE DEFENDANT EMAILED A FINAL REPORT

10:13AM TO PFIZER ON ITS WORK. THE REPORT, AS YOU SEE HERE, HAD THE
10:13AM OLD THERANOS LOGO ON IT, AND IT SET FORTH A NUMBER OF
10:14AM CONCLUSIONS THAT THERANOS HAD REACHED FROM ITS WORK.
10:14AM HOLMES CLAIMED THE ANALYZER PERFORMED WITH SUPERIOR
10:14AM PERFORMANCE, SHE CLAIMED IT DEMONSTRATED GOOD CORRELATIONS, AND
10:14AM SHE CLAIMED THAT IT HAD ROBUST FUNCTIONALITY.
10:14AM PFIZER, YOU WILL LEARN, READ THIS REPORT AND WAS NOT
10:14AM IMPRESSED. PFIZER CONCLUDED IT WAS UNCONVINCING AND THAT
10:14AM THERANOS'S DEFENSE WAS NON-INFORMATIVE AND EVASIVE.
10:14AM PFIZER TOLD THE DEFENDANT SHORTLY AFTER RECEIVING THE
10:14AM REPORT THAT IT HAD NO USE FOR THERANOS'S TECHNOLOGY. AND AFTER
10:14AM DOING SO, PFIZER NEVER DID BUSINESS WITH THERANOS AGAIN.
10:14AM BUT THE DEFENDANT GAVE AN ENTIRELY DIFFERENT AND FALSE
10:15AM STORY TO HER INVESTORS.
10:15AM IN MULTIPLE PRESENTATIONS, THE DEFENDANT TOLD INVESTORS
10:15AM THAT THERANOS SYSTEMS HAVE BEEN COMPREHENSIVELY VALIDATED BY
10:15AM 10 OF THE 15 LARGEST PHARMACEUTICAL COMPANIES.
10:15AM AND TO PROVE THIS, SHE PROVIDED TO INVESTORS EXEMPLARY
10:15AM REPORTS FROM PHARMACEUTICAL PARTNERS. ONE OF THE SO-CALLED
10:15AM EXEMPLARY REPORTS THAT SHE GAVE TO INVESTORS IS THE ONE THAT
10:15AM I'M SHOWING YOU NOW.
10:15AM THIS IS PURPORTEDLY FROM PFIZER. IT HAS THE PFIZER LOGO.
10:15AM AND THE DEFENDANT HELD THIS OUT AS DEMONSTRATING THAT
10:15AM PFIZER CONCLUDED THAT THE ANALYZER HAD SUPERIOR PERFORMANCE,
10:16AM GOOD CORRELATIONS, AND ROBUST FUNCTIONALITY.

10:16AM BUT AS YOU WILL HEAR, PFIZER DID NOT WRITE THIS. PFIZER DID NOT PUT ITS LOGO ON THIS. PFIZER DID NOT GIVE ITS PERMISSION TO PUT ITS LOGO ON THIS. PFIZER DID NOT MAKE THE CONCLUSIONS IN THIS REPORT. IN FACT, IT CAME TO THE OPPOSITE CONCLUSIONS.

YET, THE DEFENDANT GAVE THIS TO INVESTORS TO GIVE THE FALSE IMPRESSION THAT PFIZER ENDORSED THERANOS'S MINIATURE BLOOD ANALYZER.

LET ME NOW TELL YOU ABOUT THE FOURTH CATEGORY OF MISREPRESENTATION THAT YOU WILL HEAR ABOUT.

THE DEFENDANT MISLED POTENTIAL INVESTORS WITH FALSE AND MISLEADING INFORMATION ABOUT THERANOS'S FINANCIAL POSITION AND PROJECTIONS.

YOU WILL HEAR FROM THERANOS'S TOP FINANCE OFFICER, WHO WILL TELL YOU THAT THERANOS HAD APPROXIMATELY $500,000 IN REVENUE IN 2011, ZERO IN 2012, ZERO IN 2013, AND ABOUT $150,000 IN 2014.

THE DEFENDANT, HOWEVER, WAS TELLING HER INVESTORS THAT THERANOS COULD PERFORM ALL OF THE BLOOD TESTS AT A FRACTION OF THE COST, AND SHE WAS TELLING THEM AS LATE AS OCTOBER OF 2014 THAT THERANOS WOULD HAVE $140 MILLION IN REVENUE, AND $40 MILLION FROM PHARMACEUTICAL COMPANIES BY THE END OF 2014.

BUT THERANOS HAD LOST ANY SIGNIFICANT PHARMACEUTICAL BUSINESS, AND IT WAS NOWHERE ACHIEVING THE REVENUE PROJECTIONS THAT THE DEFENDANT WAS PEDDLING.

CERTIFICATE OF REPORTERS

WE, THE UNDERSIGNED OFFICIAL COURT REPORTERS OF THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA, 280 SOUTH FIRST STREET, SAN JOSE, CALIFORNIA, DO HEREBY CERTIFY:

THAT THE FOREGOING TRANSCRIPT, CERTIFICATE INCLUSIVE, IS A CORRECT TRANSCRIPT FROM THE RECORD OF PROCEEDINGS IN THE ABOVE-ENTITLED MATTER.

Irene Rodriguez

IRENE RODRIGUEZ, CSR, CRR
CERTIFICATE NUMBER 8076

Lee-Anne Shortridge

LEE-ANNE SHORTRIDGE, CSR, CRR
CERTIFICATE NUMBER 9595

DATED: SEPTEMBER 8, 2021

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA,	)	CR-18-00258-EJD
PLAINTIFF,	)	SAN JOSE, CALIFORNIA
VS.	)	VOLUME 17
ELIZABETH A. HOLMES,	)	OCTOBER 12, 2021
DEFENDANT.	)	PAGES 3001 - 3278
_____	)	**PAGES 3203 - 3278 SEALED**

TRANSCRIPT OF TRIAL PROCEEDINGS
BEFORE THE HONORABLE EDWARD J. DAVILA
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

FOR THE PLAINTIFF:

UNITED STATES ATTORNEY'S OFFICE
BY: JOHN C. BOSTIC
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SAN JOSE, CALIFORNIA 95113

BY: ROBERT S. LEACH
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OAKLAND, CALIFORNIA 94612

(APPEARANCES CONTINUED ON THE NEXT PAGE.)

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CERTIFICATE NUMBER 9595

PROCEEDINGS RECORDED BY MECHANICAL STENOGRAPHY
TRANSCRIPT PRODUCED WITH COMPUTER

02:43PM Q. AND WHAT DO YOU RECALL ABOUT THAT?
02:43PM A. AGAIN, THAT THESE MIGHT BE SOME LOW HANGING FRUIT, SO TO SPEAK, IN ORDER TO BE ABLE TO GET IN THE MARKET AND START TO UNDERSTAND THINGS LIKE CONSUMER ACCEPTANCE OF LAB IN A DRUG STORE AND OTHER LEARNINGS.
02:43PM Q. OKAY. WOULD YOU NOW TURN TO EXHIBIT 291 IN YOUR BINDER.
02:43PM THE FIRST PAGE HAS A COUPLE OF EMAILS ON IT, AND THEN THERE ARE SOME ATTACHMENTS. WOULD YOU JUST SPEND A MINUTE AND FLIP THROUGH THAT AND I'M GOING TO ASK YOU IF YOU RECOGNIZE THE ATTACHMENTS.
02:44PM A. OKAY.
02:44PM Q. DO YOU RECOGNIZE THE ATTACHMENTS?
02:44PM A. I DO.
02:44PM Q. AND WHAT ARE THE ATTACHMENTS?
02:44PM A. THESE ARE EXCERPTS FROM THE THREE PHARMA COMPANIES, DOCUMENTS THAT WERE SHARED WITH US MORE OR LESS VALIDATING THE WORK THAT THEY HAD DONE WITH THEM.
02:44PM Q. SO EARLIER WHEN YOU TALKED ABOUT SEEING SOME VALIDATION REPORTS FROM PHARMACEUTICAL COMPANIES, ARE THESE THOSE REPORTS?
02:44PM A. YES.
02:44PM Q. AND THEN THE EMAIL ON THE TOP OF THE FIRST PAGE FROM MS. HOLMES TO TWO EMPLOYEES, INCLUDING DR. ROSAN ON THIS EMAIL, YOU'RE NOT ON THIS EMAIL; IS THAT RIGHT?
02:44PM A. I'M NOT.
02:44PM Q. BUT YOU STILL SAW THESE ATTACHMENTS AT SOME POINT?

02:45PM A. YEAH. I RECALL DR. ROSAN SHARING THOSE WITH ME.

MR. SCHENK: YOUR HONOR, THE GOVERNMENT OFFERS THE FIRST EMAIL ON THE FIRST PAGE, THE ONE FROM MS. HOLMES AND THE ATTACHMENTS.

MR. DOWNEY: NO OBJECTION, YOUR HONOR.

THE COURT: THOSE ARE ADMITTED, AND THEY MAY BE PUBLISHED.

(GOVERNMENT'S EXHIBIT 291 WAS RECEIVED IN EVIDENCE.)

BY MR. SCHENK:

Q. LET'S START FIRST WITH AN EMAIL FROM MS. HOLMES ON APRIL 2010.

DO YOU SEE THAT EMAIL?

A. YES.

Q. AND IT READS "DR. JAY, ALEX.

"AS PER OUR DISCUSSION, PLEASE FIND THREE INDEPENDENT DUE DILIGENCE REPORTS ON THERANOS SYSTEMS ATTACHED TO THIS EMAIL. THESE REPORTS ARE FROM GLAXOSMITHKLINE, PFIZER, AND SCHERING-PLOUGH AFTER THEIR OWN TECHNICAL VALIDATION AND EXPERIENCE WITH THERANOS SYSTEMS IN THE FIELD. PLEASE NOTE THAT THESE DOCUMENTS ARE STRICTLY CONFIDENTIAL UNDER OUR CDA."

IN THE EMAIL, SHE WRITES "INDEPENDENT DUE DILIGENCE REPORTS." IS THAT CONSISTENT WITH YOUR UNDERSTANDING OF WHAT THESE REPORTS WERE?

A. YES.

Q. AND SHE ALSO WRITES THAT GLAXO, PFIZER, AND

CERTIFICATE OF REPORTERS

WE, THE UNDERSIGNED OFFICIAL COURT REPORTERS OF THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA, 280 SOUTH FIRST STREET, SAN JOSE, CALIFORNIA, DO HEREBY CERTIFY:

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Lee-Anne Shortridge

LEE-ANNE SHORTRIDGE, CSR, CRR
CERTIFICATE NUMBER 9595

DATED: OCTOBER 12, 2021

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA,	)	CR-18-00258-EJD
PLAINTIFF,	)	SAN JOSE, CALIFORNIA
VS.	)	VOLUME 23
ELIZABETH A. HOLMES,	)	OCTOBER 22, 2021
DEFENDANT.	)	PAGES 4318 - 4576

TRANSCRIPT OF TRIAL PROCEEDINGS
BEFORE THE HONORABLE EDWARD J. DAVILA
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

FOR THE PLAINTIFF:
UNITED STATES ATTORNEY'S OFFICE
BY: JOHN C. BOSTIC
JEFFREY B. SCHENK
150 ALMADEN BOULEVARD, SUITE 900
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BY: ROBERT S. LEACH
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OAKLAND, CALIFORNIA 94612

(APPEARANCES CONTINUED ON THE NEXT PAGE.)

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PROCEEDINGS RECORDED BY MECHANICAL STENOGRAPHY
TRANSCRIPT PRODUCED WITH COMPUTER

10:09AM A. I WAS.

10:09AM Q. YOU SHOULD HAVE A BINDER UP THERE AT THE WITNESS STAND, A WHITE BINDER, AND I'D LIKE TO DRAW YOUR ATTENTION, PLEASE, TO WHAT HAS BEEN MARKED AS TRIAL EXHIBIT 143.

10:09AM YOUR HONOR, I MOVE EXHIBIT 143 INTO EVIDENCE. I UNDERSTAND THERE'S A STIPULATION.

MR. CLINE: NO OBJECTION.

THE COURT: IT'S ADMITTED. IT MAY BE PUBLISHED.

10:09AM (GOVERNMENT'S EXHIBIT 143 WAS RECEIVED IN EVIDENCE.)

BY MR. LEACH:

10:09AM Q. DO YOU HAVE THAT IN FRONT OF YOU, SIR?

10:09AM A. I DO.

10:09AM Q. OKAY. AND IF I COULD ASK MS. HOLLIMAN TO PLEASE ZOOM IN ON THE TOP HALF OF THIS EMAIL.

10:10AM MR. WEBER, DOES THIS APPEAR TO BE AN EMAIL FROM ELIZABETH HOLMES TO TWO INDIVIDUALS NAMED AIDEN POWER AND CRAIG LIPSET?

10:10AM A. IT DOES APPEAR TO BE SO.

10:10AM Q. WHO IS AIDEN POWER?

10:10AM A. AIDEN POWER IS THE VICE PRESIDENT IN CHARGE OF MOLECULAR MEDICINE, WHICH IS A WORLDWIDE UNIT OF PFIZER.

10:10AM Q. OKAY. WERE YOU PART OF THE MOLECULAR MEDICINE GROUP?

10:10AM A. I WAS.

10:10AM Q. OKAY. AND THERE'S ANOTHER NAME, CRAIG LIPSET. WHO IS CRAIG LIPSET?

10:10AM A. CRAIG LIPSET WAS THE DIRECTOR OF CLINICAL INNOVATION AND MOLECULAR MEDICINE.

10:10AM Q. WAS HE SOMEBODY THAT YOU WORKED WITH?

10:10AM A. YES, I WORKED WITH HIM.

10:10AM Q. OKAY. HOW DID YOU GET THE ASSIGNMENT TO REVIEW THERANOS'S TECHNOLOGY IN THIS LATE 2008 TIME PERIOD?

10:10AM A. AS I REMEMBER IT, THERE WAS AN EMAIL FROM CRAIG LIPSET TO ME ASKING ME TO LOOK AT THE DIAGNOSTIC CAPABILITY OF THERANOS.

10:11AM Q. OKAY. I WANT TO FOCUS ON -- AND THE DATE OF THIS IS OCTOBER 11TH, 2008.

DO YOU SEE THAT?

10:11AM A. I DO.

10:11AM Q. AND IS THIS CONSISTENT WITH THE TIME PERIOD WHEN YOU WERE ASKED TO REVIEW THERANOS'S TECHNOLOGY?

10:11AM A. YES, I WAS ASKED AFTER THIS DATE.

10:11AM Q. OKAY. I KNOW YOU'RE NOT ON THIS EMAIL, BUT I'D LIKE TO DRAW YOUR ATTENTION TO THE THIRD PARAGRAPH.

DO YOU SEE WHERE MS. HOLMES WROTE, "I AM VERY PLEASED TO PRESENT YOU WITH THE FINAL DATA - SEE THE ATTACHED STUDY REPORT."

DO YOU SEE THAT? WE'RE IN THE THIRD PARAGRAPH, AND IT'S HIGHLIGHTED ON THE SCREEN AS WELL.

10:11AM A. YES, I SEE THIS NOW. "I AM VERY PLEASED," YES, I SEE THIS THIRD PARAGRAPH.

10:11AM Q. OKAY. AND SHE'S DRAWING ATTENTION TO AN ATTACHED STUDY

10:12AM REPORT.

CAN I PLEASE ASK YOU TO LOOK AT PAGE 3 OF THIS DOCUMENT.

A. YES.

Q. DOES THIS APPEAR TO BE THE ATTACHED STUDY REPORT THAT MS. HOLMES REFERRED TO IN THE EMAIL?

A. IT WOULD SEEM TO BE SO.

Q. OKAY. AND DO YOU SEE THE LOGO AT THE TOP WITH THERANOS REDEFINING HEALTH CARE?

A. YES.

Q. AND DO YOU SEE THE LABEL CONFIDENTIAL IN THE RIGHT CORNER ON THE TOP PAGE?

A. I DO.

Q. OKAY. THE TITLE OF THIS IS THERANOS ANGIOGENESIS STUDY REPORT.

DO YOU SEE THAT?

A. I DO.

Q. IN THIS LATE 2008 TIME PERIOD, WERE YOU MADE AWARE OF WORK BY PFIZER AND THERANOS RELATING TO AN ANGIOGENESIS PROGRAM?

A. YES.

Q. OKAY. DO YOU SEE WHERE IT SAYS "PREPARED FOR DR. AIDAN POWER, PFIZER, INC.?

A. I DO.

Q. AND DO YOU SEE THAT THERE'S, BENEATH THAT, A DOCUMENT OUTLINE?

A. I DO.

10:13AM Q. OKAY. AND I'D LIKE TO FOCUS ON THE BULLET WITH
10:13AM CONCLUSIONS. DO YOU SEE THAT? IT'S THE LAST BULLET UNDERNEATH
10:13AM DOCUMENT OUTLINE.
10:13AM AND MS. HOLLIMAN IS ZOOMING OUT ON THE SCREEN AND
10:13AM HIGHLIGHTING THAT FOR US.
10:13AM DO YOU SEE THAT?
10:13AM A. I SEE THAT.
10:13AM Q. OKAY. COULD YOU NOW PLEASE TURN TO PAGE 26.
10:14AM A. OKAY, I SEE THIS.
10:14AM Q. OKAY. DO YOU SEE THE THERANOS LOGO AT THE TOP WHERE IT
10:14AM SAYS THERANOS REDEFINING HEALTH CARE?
10:14AM A. I DO.
10:14AM Q. AND DO YOU SEE THE HEADING CONFIDENTIAL TO THE RIGHT?
10:14AM A. I DO.
10:14AM Q. AND DO YOU SEE THAT THERE ARE A NUMBER OF CONCLUSIONS
10:14AM LISTED?
10:14AM AND IF WE COULD ZOOM OUT, MS. HOLLIMAN, SO WE CAN SEE
10:14AM THERE ARE A NUMBER OF CONCLUSIONS LISTED HERE.
10:14AM DO YOU SEE THAT?
10:14AM A. YES, I DO.
10:14AM Q. LET ME DRAW YOUR ATTENTION TO NUMBER 1.
10:14AM DO YOU SEE WHERE IT SAYS, "THE THERANOS SYSTEM PERFORMED
10:14AM WITH SUPERIOR PERFORMANCE TO REFERENCE ASSAYS WHILE RUNNING IN
10:14AM A COMPLEX AMBULATORY ENVIRONMENT."
10:15AM DO YOU SEE THAT?

11:00AM THESE REPORTS ARE FROM GLAXOSMITHKLINE, PFIZER, AND
11:00AM SCHERING-PLOUGH, AFTER THEIR OWN TECHNICAL VALIDATION AND
11:00AM EXPERIENCE WITH THERANOS SYSTEMS IN THE FIELD."
11:00AM DO YOU SEE THAT LANGUAGE?
11:00AM A. I DO SEE THAT.
11:00AM Q. LET ME DRAW YOUR ATTENTION TO PAGE 8 OF THIS DOCUMENT.
11:01AM IF WE CAN ZOOM IN ON THE TOP HALF ALL OF THE WAY DOWN TO
11:01AM THE CONCLUSIONS, MS. HOLLIMAN.
11:01AM DO YOU SEE THE PFIZER LOGO UP IN THE LEFT-HAND CORNER;
11:01AM MR. WEBER?
11:01AM A. I DO.
11:01AM Q. DO YOU SEE THE THERANOS REDEFINING HEALTH CARE ON THE
11:01AM RIGHT?
11:01AM A. I DO.
11:01AM Q. AND DO YOU SEE WHERE IT SAYS THERANOS ANGIOGENESIS STUDY
11:01AM REPORT?
11:01AM A. I DO.
11:01AM Q. AND THEN THERE'S THE WORD PFIZER, INC. BENEATH THAT?
11:01AM A. I DO.
11:01AM Q. AND I'D LIKE TO NOW COMPARE THIS TO PAGE 3 OF EXHIBIT 143.
11:01AM IF WE'RE ABLE TO SPLIT THE SCREEN, MS. HOLLIMAN?
11:02AM ARE YOU ABLE TO SEE THAT ON THE SCREEN, MR. WEBER?
11:02AM A. YES, I DO SEE THE TWO PAGES.
11:02AM Q. OKAY. PRIOR TO YOUR MEETINGS WITH THE GOVERNMENT, HAD YOU
11:02AM EVER SEEN A VERSION OF THE THERANOS ANGIOGENESIS STUDY REPORT

WITH THE PFIZER LOGO ON IT?

A. NO, I HAVE NOT SEEN THAT BEFORE EXCEPT FOR IN THE INTERACTION WITH THE FEDERAL GOVERNMENT.

I HAVE NOT SEEN THIS BEFORE EXCEPT WITH THE INTERACTION WITH THE FEDERAL GOVERNMENT.

Q. OKAY. DID YOU APPROVE USE OF THE PFIZER LOGO ON THE DOCUMENT PROVIDED TO WALGREENS?

A. I DID NOT.

Q. TO YOUR KNOWLEDGE, DID ANYONE FROM PFIZER APPROVE USE OF THE PFIZER LOGO ON THE DOCUMENT PROVIDED TO WALGREENS IN EXHIBIT 29 -- EXHIBIT 291?

A. I'M NOT AWARE OF ANY PFIZER APPROVAL FOR THE USE OF THE PFIZER TRADEMARKED LOGO ON THIS DOCUMENT.

Q. OKAY. DOES IT DISAPPOINT YOU TO SEE THE PFIZER LOGO APPLIED TO THIS?

MR. CLINE: EXCUSE ME, YOUR HONOR. OBJECTION TO WHAT HE'S TALKING ABOUT.

THE COURT: SUSTAINED. SUSTAINED.

BY MR. LEACH:

Q. DID YOU APPROVE USING THE PFIZER LOGO ON ANY VERSION OF THE THERANOS ANGIOGENESIS STUDY REPORT?

A. I DID NOT.

Q. TO YOUR KNOWLEDGE, DID ANYBODY FROM PFIZER?

A. NOT THAT I'M AWARE OF.

Q. WOULD YOU HAVE APPROVED USING THE PFIZER LOGO ON THE

11:03AM THERANOS ANGIOGENESIS STUDY REPORT?

11:03AM A. I WOULD NOT BE ABLE TO APPROVE THE USE OF A PFIZER LOGO ON AN EXTERNAL DOCUMENT OF ANOTHER COMPANY. THAT IS THE PURVIEW OF PFIZER LEGAL AND TRADEMARK.

11:04AM Q. WOULD IT BE FAIR TO SAY, IN 2010 OR AFTER, THAT PFIZER ENDORSED THERANOS'S TECHNOLOGY?

11:04AM A. NO.

11:04AM Q. WOULD IT BE FAIR TO SAY, IN 2010 OR AFTER, THAT PFIZER COMPREHENSIVELY VALIDATED THERANOS'S TECHNOLOGY?

11:04AM A. NO.

11:04AM Q. CAN WE PLEASE GO TO PAGE 33 OF EXHIBIT 271, OR 291, MS. HOLLIMAN.

11:04AM AND IF WE CAN ZOOM IN ALL OF THE WAY DOWN TO CONCLUSION NUMBER 10.

11:04AM MR. WEBER, I'M DISPLAYING PAGE 33 OF EXHIBIT 291.

11:05AM AND DO YOU HAVE THAT IN FRONT OF YOU?

11:05AM A. I DO.

11:05AM Q. OKAY. AND DO YOU SEE THE PFIZER LOGO UP AT THE TOP OF THE PAGE?

11:05AM A. I DO.

11:05AM Q. AND DO YOU SEE THE THERANOS LOGO TO THE RIGHT?

11:05AM A. I DO.

11:05AM Q. AND DO YOU SEE A NUMBER OF CONCLUSIONS THAT ARE LISTED IN THIS DOCUMENT?

11:05AM A. I DO.

11:05AM Q. OKAY. DID YOU APPROVE USE OF THE PFIZER LOGO ON THIS PAGE OF THE DOCUMENT PROVIDED TO WALGREENS?

11:05AM A. NO, I DID NOT.

11:05AM Q. TO YOUR KNOWLEDGE, DID ANYONE FROM PFIZER DO THAT?

11:05AM A. NOT THAT I'M AWARE OF.

11:05AM Q. OKAY. THIS SAYS -- THE FIRST CONCLUSION, "THE THERANOS SYSTEM PERFORMED WITH SUPERIOR PERFORMANCE TO REFERENCE ASSAYS WHILE RUNNING IN A COMPLEX AMBULATORY ENVIRONMENT."

11:05AM DO YOU SEE THAT?

11:05AM A. I DO.

11:05AM Q. AND DO YOU AGREE WITH THAT?

11:05AM A. NO, I DO NOT.

11:05AM Q. TO YOUR KNOWLEDGE, DID ANYONE FROM PFIZER AGREE WITH THAT?

11:06AM A. NOT THAT I'M AWARE OF THAT.

11:06AM MR. CLINE: EXCUSE ME, YOUR HONOR. I APOLOGIZE FOR INTERRUPTING, MR. WEBER.

11:06AM I THINK -- ASSUMING WE'RE GOING TO GO THROUGH THE WHOLE LIST HERE, THIS IS 702 TERRITORY AND I OBJECT ON THAT BASIS.

11:06AM THE COURT: IS THE QUESTION GOING TO BE SIMILAR TO THE ONE THAT YOU JUST ASKED, WHETHER OR NOT HE APPROVED IT OR WHETHER --

11:06AM MR. LEACH: OR WHETHER OR NOT IT WAS HIS CONCLUSION, HIS THOUGHTS AT THE TIME.

11:06AM THE COURT: RIGHT. RIGHT.

11:06AM NO, HE CAN TESTIFY ABOUT THAT.

THE OBJECTION IS OVERRULED ON 702 GROUNDS.

BY MR. LEACH:

Q. DID YOU AGREE WITH THAT AT THE TIME, MR. WEBER, CONCLUSION NUMBER 1?

A. NO, I DID NOT AGREE WITH THIS CONCLUSION.

Q. OKAY. TO YOUR KNOWLEDGE, DID ANYONE FROM PFIZER -- DID ANYONE FROM PFIZER TELL YOU THAT THEY AGREED WITH THAT CONCLUSION?

A. NO ONE FROM PFIZER TOLD ME THAT THEY AGREED WITH THIS CONCLUSION AS I REMEMBER IT.

Q. OKAY. DID YOU EVER TELL ANYONE FROM THERANOS THAT THIS WAS PFIZER'S CONCLUSION AFTER REVIEWING THERANOS'S TECHNOLOGY?

A. NO, I DID NOT.

Q. LET ME DRAW YOUR ATTENTION TO NUMBER 5.

DO YOU SEE WHERE IT SAYS, "INTER-SYSTEM ACCURACY IS EXCELLENT AND WAS DEMONSTRATED ON A PLATFORM WITH SUPERIOR PERFORMANCE SPECIFICATIONS TO REFERENCE METHODS."

DO YOU SEE THAT?

A. I DO.

Q. AND WAS THAT YOUR CONCLUSION?

A. NO, IT WAS NOT.

Q. TO YOUR KNOWLEDGE, WAS THAT THE CONCLUSION OF ANYBODY AT PFIZER?

A. NOT THAT I'M AWARE OF. I'M NOT AWARE OF ANYONE AT PFIZER THAT AGREED WITH THIS CONCLUSION, OR WOULD.

11:07AM Q. DID YOU EVER TELL SOMEBODY AT THERANOS THAT THIS WAS PFIZER'S CONCLUSION?

11:07AM A. NO, I DID NOT.

11:07AM Q. ARE ANY OF THE CONCLUSIONS LISTED ON PAGE 29 CONCLUSIONS THAT YOU HAD REACHED AFTER YOUR REVIEW OF THERANOS'S TECHNOLOGY?

11:07AM A. NO, THEY ARE NOT.

11:08AM Q. TO YOUR KNOWLEDGE, AFTER 2010 DID PFIZER DO ANY WORK, REVENUE GENERATING WORK WITH THERANOS?

11:08AM A. I'M NOT AWARE OF ANY REVENUE GENERATING WORK BY THERANOS WITH PFIZER AT THAT TIME.

11:08AM Q. TO YOUR KNOWLEDGE, AFTER THIS ANGIOGENESIS PROGRAM, DID THERANOS -- OR PFIZER PAY ANY MONEY TO THERANOS?

11:08AM A. I'M NOT AWARE OF ANY MONIES BEING PAID TO THERANOS OTHER THAN FOR THAT ANGIOGENESIS STUDY.

11:08AM Q. THE ANGIOGENESIS STUDY THAT YOU WERE REVIEWING IN LATE 2008 AND THE EARLY PART OF 2009?

11:08AM A. YES.

11:08AM Q. TO YOUR KNOWLEDGE, DID PFIZER AND THERANOS HAVE ANY MEANINGFUL BUSINESS DEALINGS AFTER 2008?

11:08AM A. TO MY AWARENESS AND -- THERE WAS NO FURTHER INTERACTION IN ANY MEANINGFUL WAY BETWEEN THERANOS AND PFIZER.

11:09AM Q. DO YOU AGREE WITH THE STATEMENT THAT PFIZER VALIDATED THERANOS'S TECHNOLOGY?

11:09AM A. NO, I DO NOT.

CERTIFICATE OF REPORTERS

WE, THE UNDERSIGNED OFFICIAL COURT REPORTERS OF THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA, 280 SOUTH FIRST STREET, SAN JOSE, CALIFORNIA, DO HEREBY CERTIFY:

THAT THE FOREGOING TRANSCRIPT, CERTIFICATE INCLUSIVE, IS A CORRECT TRANSCRIPT FROM THE RECORD OF PROCEEDINGS IN THE ABOVE-ENTITLED MATTER.

Irene Rodriguez

IRENE RODRIGUEZ, CSR, CRR
CERTIFICATE NUMBER 8076

Lee-Anne Shortridge

LEE-ANNE SHORTRIDGE, CSR, CRR
CERTIFICATE NUMBER 9595

DATED: OCTOBER 22, 2021

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA,	)	CR-18-00258-EJD
PLAINTIFF,	)	SAN JOSE, CALIFORNIA
VS.	)	VOLUME 24
ELIZABETH A. HOLMES,	)	OCTOBER 26, 2021
DEFENDANT.	)	PAGES 4577 - 4869
	)	**PAGES 4674 TO 4677 SEALED**

TRANSCRIPT OF TRIAL PROCEEDINGS
BEFORE THE HONORABLE EDWARD J. DAVILA
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

FOR THE PLAINTIFF: UNITED STATES ATTORNEY'S OFFICE
BY: JOHN C. BOSTIC
JEFFREY B. SCHENK
150 ALMADEN BOULEVARD, SUITE 900
SAN JOSE, CALIFORNIA 95113

BY: ROBERT S. LEACH
KELLY VOLKAR
1301 CLAY STREET, SUITE 340S
OAKLAND, CALIFORNIA 94612

(APPEARANCES CONTINUED ON THE NEXT PAGE.)

OFFICIAL COURT REPORTERS:
IRENE L. RODRIGUEZ, CSR, RMR, CRR
CERTIFICATE NUMBER 8074
LEE-ANNE SHORTRIDGE, CSR, CRR
CERTIFICATE NUMBER 9595

PROCEEDINGS RECORDED BY MECHANICAL STENOGRAPHY
TRANSCRIPT PRODUCED WITH COMPUTER

THAT THIS POWERPOINT REFERRED YOU TO?

A. YES.

Q. AND DID YOU MAKE AN EFFORT TO REVIEW WHATEVER PUBLIC INFORMATION YOU COULD FIND ABOUT THERANOS?

A. YES.

Q. LET ME DRAW YOUR ATTENTION, PLEASE, TO PAGE 103 OF THIS DOCUMENT.

IS THIS A PORTION OF THE MATERIALS IN THE BINDER THAT YOU REVIEWED, MS. PETERSON?

A. YES.

Q. OKAY. AND DO YOU SEE WHERE IT SAYS, "EXEMPLARY REPORTS FROM PHARMACEUTICAL PARTNERS"?

A. YES.

Q. PLEASE LOOK AT THE NEXT PAGE, PAGE 140, OR 104.

AND IF WE CAN ZOOM IN, MS. HOLLIMAN, ON EVERYTHING DOWN TO THE WORD "CONCLUSIONS" AND THE THREE BULLETS. THERE YOU GO.

THANK YOU.

DOES THIS APPEAR TO BE SOMETHING CALLED "THERANOS ANGIOGENESIS STUDY REPORT"?

A. YES.

Q. AND DO YOU SEE THE PFIZER LOGO UP IN THE LEFT-HAND CORNER?

A. YES.

Q. AND DO YOU SEE THE THERANOS LOGO IN THE RIGHT-HAND CORNER?

A. YES.

Q. OKAY. DID YOU BELIEVE THIS REPORT WAS PREPARED BY PFIZER?

CERTIFICATE OF REPORTERS

WE, THE UNDERSIGNED OFFICIAL COURT REPORTERS OF THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA, 280 SOUTH FIRST STREET, SAN JOSE, CALIFORNIA, DO HEREBY CERTIFY:

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Irene Rodriguez

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Lee-Anne Shortridge

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CERTIFICATE NUMBER 9595

DATED: OCTOBER 26, 2021

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA,	)	CR-18-00258-EJD
PLAINTIFF,	)	SAN JOSE, CALIFORNIA
VS.	)	VOLUME 36
ELIZABETH A. HOLMES,	)	NOVEMBER 2, 2021
DEFENDANT.	)	PAGES 4903 - 5186

TRANSCRIPT OF TRIAL PROCEEDINGS
BEFORE THE HONORABLE EDWARD J. DAVILA
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

FOR THE PLAINTIFF: UNITED STATES ATTORNEY'S OFFICE
BY: JOHN C. BOSTIC
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(APPEARANCES CONTINUED ON THE NEXT PAGE.)

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PROCEEDINGS RECORDED BY MECHANICAL STENOGRAPHY
TRANSCRIPT PRODUCED WITH COMPUTER

12:22PM A. BECAUSE SCHERING-PLOUGH HAD PAID $279,000 FOR THIS WORK.
12:22PM WE HAD EXPECTED TO RECEIVE IT AT THAT MAY DUE DILIGENCE
12:22PM MEETING, AND WE DID NOT.
12:22PM Q. ABOVE THIS EMAIL, MR. FRENZEL FORWARDS IT TO MS. HOLMES.
12:22PM DO YOU SEE THAT, FORWARDS YOUR EMAIL TO MS. HOLMES?
12:22PM A. YES.
12:22PM Q. IF YOU'LL NOW TURN TO TAB 259.
12:22PM YOUR HONOR, THE GOVERNMENT OFFERS 259 PURSUANT TO
12:22PM STIPULATION.
12:22PM MR. CLINE: NO OBJECTION.
12:22PM THE COURT: IT'S ADMITTED. IT MAY BE PUBLISHED.
12:22PM (GOVERNMENT'S EXHIBIT 259 WAS RECEIVED IN EVIDENCE.)
12:22PM BY MR. SCHENK:
12:22PM Q. THE FIRST DOCUMENT IN 259 AT THE BOTTOM APPEARS TO BE AN
12:22PM EMAIL FROM MR. FRENZEL TO YOU.
12:23PM DO YOU SEE THAT?
12:23PM A. YES.
12:23PM Q. AND LET ME NOTE THAT THIS IS NOW IN DECEMBER. THE EMAIL
12:23PM THAT WE WERE JUST TALKING ABOUT WAS IN JUNE; IS THAT RIGHT?
12:23PM A. THAT'S RIGHT.
12:23PM Q. SO ABOUT SIX MONTHS LATER, MR. FRENZEL WRITES, "HI
12:23PM CONNIE."
12:23PM THE SUBJECT WAS VALIDATION REPORT?
12:23PM A. UH-HUH.
12:23PM Q. WAS THAT A YES?

12:23PM A. YES.

12:23PM Q. "HI CONNIE, I WAS ASKED TO SEND THIS REPORT ON TO YOU, AND IF YOU CAN FORWARD TO THE PROPER PEOPLE. AFTER YOU AND YOUR GROUP HAVE AN OPPORTUNITY TO GO THROUGH IT, LET US KNOW IF YOU WOULD LIKE TO ARRANGE A PHONE CONFERENCE TO DISCUSS THE RESULTS."

DO YOU SEE THAT?

12:23PM A. I DO.

12:23PM Q. AND THEN ABOVE THIS EMAIL, MR. FRENZEL FORWARDS IT ALMOST TWO MONTHS LATER, THE END OF JANUARY 2010, TO SOMEONE NAMED DENNIS YAM.

DO YOU SEE THAT?

12:23PM A. YES.

12:23PM Q. LET'S GO NOW TO THE ATTACHMENT. LET'S START ON PAGE 3.

WHAT IS THIS DOCUMENT? WHAT ARE WE LOOKING AT?

12:23PM A. SO THIS WAS THE VALIDATION REPORT THAT THERANOS HAD PROVIDED.

12:23PM Q. OKAY. THE REPORT THAT YOU MENTIONED EXPECTING TO SEE IN MAY AND WRITING ABOUT IN JUNE?

12:24PM A. CORRECT.

12:24PM Q. OKAY. AND ON THIS PAGE, IF WE COULD ZOOM OUT, IN THE UPPER LEFT CORNER, DO YOU SEE THERANOS'S LOGO?

12:24PM A. I DO.

12:24PM Q. IN THE UPPER RIGHT CORNER, DO YOU SEE A SCHERING-PLOUGH LOGO?

12:24PM A. I DO NOT.

12:24PM Q. IF WE COULD NOW TURN TO PAGE 5. THERE IS DATA ON PAGE 5. DO YOU SEE THAT?

12:24PM A. YES.

12:24PM Q. AND IS THIS SCHERING-PLOUGH DATA?

12:24PM A. NO.

12:24PM Q. WHO GENERATED THIS DATA?

12:24PM A. THERANOS.

12:24PM Q. ON PAGE 19, IF YOU'LL TURN TO PAGE 19, THERE'S A SECTION ENTITLED CONCLUSIONS.

12:24PM DO YOU SEE THAT?

12:24PM A. I DO.

12:24PM Q. AND WHOSE CONCLUSIONS ARE THESE?

12:24PM A. THOSE WOULD HAVE BEEN THERANOS'S CONCLUSIONS SINCE THEY WROTE THE REPORT.

12:24PM Q. DID -- LET ME FOCUS YOUR ATTENTION ON THE VERY FIRST SENTENCE OF THE CONCLUSIONS. IT READS, "THE THERANOS'S IL-6, TNF-A, AND CRP ASSAY MULTIPLEX HAS BEEN SHOWN TO GIVE ACCURATE AND PRECISE RESULTS FOR THREE INDEPENDENTLY CALIBRATED CARTRIDGE LOTS AND ALL THE MANY INSTRUMENTS USED."

12:25PM IS THAT A CONCLUSION THAT YOU REACHED?

12:25PM A. NO.

12:25PM Q. TO YOUR KNOWLEDGE, IS THAT A CONCLUSION THAT ANYBODY AT SCHERING-PLOUGH REACHED?

12:25PM A. NO.

12:25PM Q. WHEN YOU RECEIVED THIS DOCUMENT, YOU SAW THAT THE FIRST
12:25PM PAGE OF THIS EXHIBIT WAS MR. FRENZEL SENDING THIS TO YOU IN
12:25PM DECEMBER, DID YOU WRITE HIM BACK AND SAY, I AGREE WITH THESE
12:25PM CONCLUSIONS?
12:25PM A. NO.
12:25PM Q. WAS THERE EVER AN OCCASION WHEN YOU SAID THESE CONCLUSIONS
12:25PM ARE ACCURATE?
12:25PM A. NO.
12:25PM Q. TO YOUR KNOWLEDGE, WAS THERE EVER AN OCCASION WHEN ANYBODY
12:25PM AT SCHERING-PLOUGH SAID THIS DOCUMENT OR THESE CONCLUSIONS ARE
12:25PM ACCURATE?
12:25PM A. NO.
12:25PM Q. WOULD YOU NOW TURN TO PAGE 262? I'M SORRY, EXHIBIT 262.
12:26PM YOUR HONOR, THE GOVERNMENT OFFERS 262 TO PURSUANT TO
12:26PM STIPULATION.
12:26PM MR. CLINE: NO OBJECTION.
12:26PM THE COURT: IT'S ADMITTED. IT MAY BE PUBLISHED.
12:26PM (GOVERNMENT'S EXHIBIT 262 WAS RECEIVED IN EVIDENCE.)
12:26PM BY MR. SCHENK:
12:26PM Q. YOU'LL SEE THIS IS A CONTINUATION OF A PRIOR EMAIL CHAIN.
12:26PM IF YOU START ON THE PAGE 2, THERE IS THAT EMAIL FROM
12:26PM MR. FRENZEL TO YOU IN DECEMBER WITH A VALIDATION REPORT.
12:26PM DO YOU SEE THAT?
12:26PM A. YES.
12:26PM Q. AND NOW IF WE COME BACK TO THE FIRST PAGE OF THIS EXHIBIT

12:29PM WOULD YOU CALL THAT SCHERING-PLOUGH'S OWN TECHNICAL VALIDATION?
A. NO.
Q. WE ALSO HAVE TALKED ABOUT SOME BETA TESTING. WOULD YOU DESCRIBE FOR THE JURY WHAT THAT WAS?
A. YES. BETA TESTING WAS WE HAD TWO INSTRUMENTS IN THE LABORATORY AND WE HAD A VOLUNTEER FROM THE LAB PROVIDE A BLOOD SAMPLE AND WE MEASURED C REACTIVE PROTEIN.
TO MY RECOLLECTION IT WAS A SINGLE DETERMINATION.
Q. WHAT DOES THAT MEAN, A SINGLE DETERMINATION?
A. IT MEANS WE TESTED ONE SAMPLE ONCE.
Q. THE PHRASE IN THIS EMAIL THAT I HIGHLIGHTED FOR YOU, SCHERING-PLOUGH'S OWN TECHNICAL VALIDATION, YOU SAID THAT WOULD NOT BE ACCURATE FOR THE REPORT, THE VALIDATION REPORT?
A. THAT IS CORRECT.
Q. WOULD THAT BE ACCURATE FOR THE BETA TESTING?
A. NO, IT WOULD NOT.
Q. WHY?
A. TOO FEW SAMPLES, NO PROTOCOL WITH PREDEFINED ACCEPTANCE CRITERIA.
Q. IF YOU'LL TURN TO IN EXHIBIT 291, PAGE 34 OF THE EXHIBIT.
DO YOU SEE A COPY OF THE THERANOS MULTIPLEXED VALIDATION AND A REFERENCE AGAIN TO IL-6, TNF-ALPHA, AND CRP?
A. I DO.
Q. AND AGAIN, IS THIS THE VALIDATION REPORT THAT YOU HAVE TESTIFIED ABOUT PREVIOUSLY FROM TODAY?

12:30PM A. YES.

12:30PM Q. AND IN THE UPPER LEFT-HAND CORNER, WHAT DO YOU SEE?

12:30PM A. I SEE THE SCHERING-PLOUGH LOGO.

12:30PM Q. OKAY.

12:30PM IF I COULD, MS. HOLLIMAN, IF IT'S POSSIBLE IF WE COULD BRING UP 259, PAGE 3, AND EXHIBIT 291, PAGE 34 AT THE SAME TIME.

12:31PM THE DOCUMENT ON THE LEFT, DR. CULLEN, IS 259, PAGE 3.

12:31PM IS THAT THE VERSION THAT WAS EMAILED TO YOU BY MR. FRENZEL?

12:31PM A. YES.

12:31PM Q. AND WHAT I'M SHOWING ON THE RIGHT, IS THAT A VERSION THAT WAS SENT AT LEAST IN THE EMAIL TO WALGREENS?

12:31PM A. I DON'T KNOW WHAT DOCUMENT WOULD HAVE BEEN SENT TO WALGREENS.

12:31PM Q. IN EXHIBIT 291 THAT I'VE SHOWED YOU, THOUGH, IS THAT --

12:31PM A. YES, YES.

12:31PM Q. -- IT IS THAT SAME DOCUMENT; IS THAT RIGHT?

12:31PM A. YES.

12:31PM Q. AND MS. HOLLIMAN, IF WE COULD ALSO BRING UP 259, PAGE 19, AND 291, PAGE 51.

12:31PM DR. CULLEN, A MOMENT AGO I READ FOR YOU THE CONCLUSION SECTION IN THE VALIDATION REPORT THAT WAS SENT TO SCHERING-PLOUGH.

12:32PM DO YOU RECALL THAT?

12:32PM A. YES.

12:32PM Q. AND THAT'S APPEARING NOW AT THE TOP OF THE SCREEN, THAT

12:32PM THE THERANOS MULTIPLEXED ASSAYS WERE SHOWN TO GIVE ACCURATE AND

12:32PM PRECISE RESULTS FOR THREE INDEPENDENTLY CALIBRATED CARTRIDGE

12:32PM LOTS.

12:32PM DO YOU SEE THAT?

12:32PM A. YES.

12:32PM Q. AND I THINK YOU TOLD US THAT WAS NOT A SCHERING-PLOUGH

12:32PM CONCLUSION; IS THAT RIGHT?

12:32PM A. THAT IS CORRECT.

12:32PM Q. AND IN EXHIBIT 291, THE VERSION THAT WAS ATTACHED TO THE

12:32PM WALGREENS EMAIL, THE FIRST SENTENCE OF THE CONCLUSIONS NOW

12:32PM READS, "THE THERANOS IL-6, TNF-ALPHA, CRP ASSAYS MULTIPLEX HAS

12:32PM BEEN SHOWN TO GIVE MORE ACCURATE AND PRECISE RESULTS FOR THREE

12:32PM INDEPENDENTLY CALIBRATED CARTRIDGE LOTS AND ALL OF THE MANY

12:32PM INSTRUMENTS USED THAN CURRENT 'GOLD STANDARD' REFERENCE

12:32PM METHODS."

12:32PM DID I READ THAT RIGHT?

12:32PM A. YES.

12:32PM Q. IT MAY GO WITHOUT SAYING, BUT YOU DID NOT APPROVE THE

12:32PM VERSION ON TOP, THE ONE THAT WAS SENT TO YOU; IS THAT CORRECT?

12:33PM A. THAT'S CORRECT.

12:33PM Q. AND THE ENHANCED CONCLUSION, IS THAT SOMETHING THAT YOU

12:33PM WOULD AGREE WITH?

12:33PM A. NO.

Q. IS THAT SOMETHING THAT, TO YOUR KNOWLEDGE, ANYBODY FROM SCHERING-PLOUGH AGREED WITH?

A. NO.

MR. SCHENK: YOUR HONOR, MAY I HAVE ONE MOMENT?

THE COURT: YES.

(DISCUSSION AMONGST GOVERNMENT COUNSEL OFF THE RECORD.)

MR. SCHENK: THANK YOU. NO FURTHER QUESTIONS.

THE COURT: MR. CLINE, DO YOU HAVE CROSS-EXAMINATION?

MR. CLINE: I DO.

CROSS-EXAMINATION

BY MR. CLINE:

Q. DR. CULLEN, GOOD AFTERNOON.

A. GOOD AFTERNOON.

Q. MY NAME IS JOHN CLINE AND I'M ONE OF THE LAWYERS FOR MS. HOLMES.

LET ME START BY TAKING CARE A LITTLE BIT OF ADMINISTRATIVE STUFF HERE.

YOUR HONOR, MAY I APPROACH THE WITNESS?

THE COURT: YES.

BY MR. CLINE:

Q. DR. CULLEN, I'M GOING TO HAND YOU ANOTHER BINDER --

A. OKAY.

Q. -- WHICH HAS SOME OTHER EXHIBITS IN IT THAT I WILL BE REFERRING YOU TO AS WE GO ALONG (HANDING.)

CERTIFICATE OF REPORTER

I, THE UNDERSIGNED OFFICIAL COURT REPORTER OF THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA, 280 SOUTH FIRST STREET, SAN JOSE, CALIFORNIA, DO HEREBY CERTIFY:

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Irene Rodriguez

IRENE RODRIGUEZ, CSR, RMR, CRR
CERTIFICATE NUMBER 8074

DATED: NOVEMBER 2, 2021

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA,	)	CR-18-00258-EJD
PLAINTIFF,	)	SAN JOSE, CALIFORNIA
VS.	)	VOLUME 38
ELIZABETH A. HOLMES,	)	NOVEMBER 23, 2021
DEFENDANT.	)	PAGES 7444 - 7681

TRANSCRIPT OF TRIAL PROCEEDINGS
BEFORE THE HONORABLE EDWARD J. DAVILA
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

FOR THE PLAINTIFF: UNITED STATES ATTORNEY'S OFFICE
BY: JOHN C. BOSTIC
JEFFREY B. SCHENK
150 ALMADEN BOULEVARD, SUITE 900
SAN JOSE, CALIFORNIA 95113

BY: ROBERT S. LEACH
KELLY VOLKAR
1301 CLAY STREET, SUITE 340S
OAKLAND, CALIFORNIA 94612

(APPEARANCES CONTINUED ON THE NEXT PAGE.)

OFFICIAL COURT REPORTERS:
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CERTIFICATE NUMBER 8074
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CERTIFICATE NUMBER 9595

PROCEEDINGS RECORDED BY MECHANICAL STENOGRAPHY
TRANSCRIPT PRODUCED WITH COMPUTER

09:44AM Q. NOW, DURING THE COURSE OF THIS MEETING IN 2010 -- WHAT
09:44AM MONTH WAS THIS MEETING, IF YOU RECALL?
09:45AM A. JUST LOOKING BACK AT THE EMAIL, I THINK IT WAS IN MARCH.
09:45AM END OF MARCH.
09:45AM Q. NOW, DID WALGREENS EXPRESS AFTER THAT MEETING THAT THEY
09:45AM MIGHT BE INTERESTED IN EXPLORING A RELATIONSHIP WITH THERANOS?
09:45AM A. YES.
09:45AM Q. DID THEY ALSO EXPRESS TO THERANOS THAT THEY WOULD LIKE TO
09:45AM DO SOME DUE DILIGENCE TO EVALUATE WHETHER THERANOS WAS A
09:45AM PARTNER WITH WHOM WALGREENS THOUGHT IT COULD WORK?
09:45AM A. THEY DID.
09:45AM Q. OKAY. NOW, I WANT TO FOCUS ON TWO REPORTS FROM
09:45AM PHARMACEUTICAL COMPANIES THAT YOU SENT TO WALGREENS IN 2010.
09:45AM DO YOU RECALL THAT THERE'S BEEN TESTIMONY ABOUT THOSE
09:45AM REPORTS?
09:45AM A. I DO.
09:45AM Q. ONE OF THOSE REPORTS WAS FROM SCHERING-PLOUGH; CORRECT?
09:46AM A. YES.
09:46AM Q. AND THE OTHER REPORT WAS FROM PFIZER; CORRECT?
09:46AM A. YES.
09:46AM Q. WHY DID YOU CHOOSE TO SEND THE SCHERING-PLOUGH REPORT TO
09:46AM WALGREENS AS PART OF ITS DUE DILIGENCE?
09:46AM A. BECAUSE WE HAD WORKED WITH SCHERING-PLOUGH TO ESTABLISH
09:46AM VERY RIGOROUS STANDARDS AGAINST WHICH TO VALIDATE OUR TESTS,
09:46AM AND WE HAD RUN THOUSANDS OF CARTRIDGES SHOWING NOT ONLY THAT WE

09:46AM COULD MULTIPLEX THE TESTS ON A SINGLE CARTRIDGE, BUT ALSO THAT
09:46AM WE COULD MEASURE MARKERS AT REALLY LOW LEVELS THAT ARE REALLY
09:46AM HARD TO DO, AND I WANTED TO SHARE THAT DATA.
09:46AM Q. WHEN YOU SAY "MULTIPLEX," WHAT DO YOU MEAN?
09:46AM A. SORRY. THE ABILITY TO RUN THE SAME TESTS ON A SINGLE
09:46AM CARTRIDGE, OR MULTIPLE TESTS ON A SINGLE CARTRIDGE AT THE SAME
09:46AM TIME.
09:46AM Q. OKAY. AND WHY DID YOU CHOOSE TO SHARE THE PFIZER REPORT
09:46AM WITH WALGREENS AS PART OF ITS DUE DILIGENCE PROCESS?
09:46AM A. BECAUSE, AGAIN, WE HAD WORKED WITH PFIZER FOR YEARS TO
09:47AM DEVELOP A STUDY THAT WOULD MEASURE THESE VERY COMPLICATED
09:47AM CANCER MARKERS IN PEOPLE'S HOMES, THE DEVICES WORKED, AND I
09:47AM THOUGHT THE DATA WAS REALLY GOOD, AND I WANTED TO SHARE IT WITH
09:47AM THEM.
09:47AM Q. DO YOU RECALL THAT THERE HAS BEEN TESTIMONY TO THE EFFECT
09:47AM THAT THE LOGOS OF THOSE PHARMACEUTICAL COMPANIES WERE ADDED TO
09:47AM THE TOP OF THOSE DOCUMENTS?
09:47AM A. I DO.
09:47AM Q. AND WHO ADDED THE LOGOS OF THOSE COMPANIES TO THE TOP OF
09:47AM THOSE DOCUMENTS?
09:47AM A. I DID.
09:47AM Q. WHEN DID YOU DO THAT?
09:47AM A. JUST BEFORE SENDING THEM TO WALGREENS.
09:47AM Q. WHY DID YOU DO THAT?
09:47AM A. BECAUSE THIS WORK WAS DONE IN PARTNERSHIP WITH THOSE

09:47AM COMPANIES, AND I WAS TRYING TO CONVEY THAT.
09:47AM Q. YOU'VE HEARD TESTIMONY FROM WITNESSES IN THIS CASE THAT
09:47AM THEY THOUGHT THAT THE REPORTS THAT YOU SENT HAD BEEN PREPARED
09:47AM BY THOSE PHARMACEUTICAL COMPANIES.
09:47AM DO YOU RECALL THAT?
09:47AM A. I DO.
09:47AM Q. DID YOU INTEND TO GIVE THAT IMPRESSION WHEN YOU
09:47AM TRANSMITTED THOSE REPORTS TO WALGREENS?
09:48AM A. NO. BUT I'VE HEARD THAT TESTIMONY IN THIS CASE, AND I
09:48AM WISH I HAD DONE IT DIFFERENTLY.
09:48AM Q. DID YOU -- AS OF 2010, SCHERING-PLOUGH NO LONGER EXISTED
09:48AM AS AN INDEPENDENT PHARMACEUTICAL COMPANY; IS THAT RIGHT?
09:48AM A. CORRECT.
09:48AM Q. BUT PFIZER DID; RIGHT?
09:48AM A. YES.
09:48AM Q. DID YOU TRY TO CONCEAL FROM PFIZER THAT YOU HAD ADDED
09:48AM PFIZER'S LOGO TO THE TOP OF THE REPORT THAT YOU SENT TO
09:48AM WALGREENS IN 2010?
09:48AM A. NOT AT ALL.
09:48AM Q. LET ME ASK YOU TO LOOK AT EXHIBIT 15048.
09:48AM YOUR HONOR, I'M NOT SURE IF THIS IS IN YOUR NOTEBOOK?
09:48AM THE COURT: I DON'T BELIEVE IT IS.
09:48AM MR. DOWNEY: BUT MR. LEACH HAS A COPY.
09:48AM THE COURT: THANK YOU.
09:48AM THE WITNESS: I DON'T KNOW IF I HAVE IT.

CERTIFICATE OF REPORTERS

WE, THE UNDERSIGNED OFFICIAL COURT REPORTERS OF THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA, 280 SOUTH FIRST STREET, SAN JOSE, CALIFORNIA, DO HEREBY CERTIFY:

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CERTIFICATE NUMBER 8076

Lee-Anne Shortridge

LEE-ANNE SHORTRIDGE, CSR, CRR
CERTIFICATE NUMBER 9595

DATED: NOVEMBER 23, 2021

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA,	)	CR-18-00258-EJD
PLAINTIFF,	)	SAN JOSE, CALIFORNIA
VS.	)	VOLUME 40
ELIZABETH A. HOLMES,	)	NOVEMBER 30, 2021
DEFENDANT.	)	PAGES 7922 - 8213

TRANSCRIPT OF TRIAL PROCEEDINGS
BEFORE THE HONORABLE EDWARD J. DAVILA
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

FOR THE PLAINTIFF:
UNITED STATES ATTORNEY'S OFFICE
BY: JOHN C. BOSTIC
JEFFREY B. SCHENK
150 ALMADEN BOULEVARD, SUITE 900
SAN JOSE, CALIFORNIA 95113

BY: ROBERT S. LEACH
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(APPEARANCES CONTINUED ON THE NEXT PAGE.)

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PROCEEDINGS RECORDED BY MECHANICAL STENOGRAPHY
TRANSCRIPT PRODUCED WITH COMPUTER

Q. 259?
A. I THINK SO. I DON'T HAVE THEM IN FRONT OF ME, BUT I ASSUME SO.
Q. OKAY. AND, MS. HOLLIMAN, IF WE COULD PLEASE ZOOM OUT.
THERE ARE SOME DIFFERENCES IN THE CONCLUSIONS PARAGRAPH OF THIS -- OF THESE TWO DOCUMENTS.
DO YOU SEE HOW ON 291 IT SAYS, "THE THERANOS IL-6, TNF-A, CRP ASSAY MULTIPLEX HAS BEEN SHOWN TO GIVE MORE ACCURATE AND PRECISE RESULTS FOR THREE INDEPENDENTLY CALIBRATED CARTRIDGE LOTS AND ALL OF THE MANY INSTRUMENTS USED THAN CURRENT 'GOLD STANDARD' REFERENCE METHODS."
DO YOU SEE THAT LANGUAGE?
A. I DO.
Q. AND I PROBABLY DIDN'T READ THAT AS WELL AS I SHOULD HAVE.
BUT DO YOU SEE THAT LANGUAGE?
A. I DO.
Q. AND DO YOU SEE HOW THOSE WORDS, "GOLD STANDARD REFERENCE METHODS," ARE NOT ON THE CONCLUSIONS IN THE REPORT THAT GOES TO SCHERING-PLOUGH?
A. YES.
Q. DID YOU ADD THOSE WORDS?
A. I THINK SO.
Q. OKAY. AND YOU DIDN'T TESTIFY TO THAT IN YOUR DIRECT EXAMINATION; IS THAT CORRECT?
A. I DON'T THINK SO.

03:17PM Q. IS MAKING THE CHANGE TO THE CONCLUSIONS PARAGRAPH ALSO
03:18PM SOMETHING THAT YOU WISH YOU HAD DONE DIFFERENTLY?
03:18PM A. I THINK THIS WAS ACCURATELY REFLECTING THE DATA IN THE
03:18PM DOCUMENT.
03:18PM BUT, YES, I THINK THAT THE WAY THAT THESE REPORTS WERE
03:18PM COMMUNICATED, I ABSOLUTELY WISH IT HAD BEEN BOLDED THAT THEY
03:18PM WERE WRITTEN BY US.
03:18PM Q. LET'S TALK ABOUT GSK.
03:18PM DO YOU RECALL TESTIFYING ABOUT GSK?
03:18PM A. I DO.
03:18PM Q. OKAY. AND IF WE COULD LOOK AT EXHIBIT 291, PAGE 2.
03:18PM IS THIS ANOTHER ONE OF THE ATTACHMENTS THAT WENT TO
03:18PM WALGREENS?
03:18PM A. YES.
03:18PM Q. AND DO YOU SEE THE GLAXOSMITHKLINE LOGO IN THE TOP LEFT
03:19PM PORTION OF THIS DOCUMENT?
03:19PM A. I DO.
03:19PM Q. AND DO YOU SEE THE HEADING "EXCERPTS FROM GSK METABOLIC
03:19PM STUDY REPORT"?
03:19PM A. I DO.
03:19PM Q. NOW, GSK, UNLIKE SCHERING-PLOUGH AND PFIZER, GSK HAD
03:19PM PROVIDED TO THERANOS AN EMAIL TITLED "THERANOS EVALUATION."
03:19PM YOU RECALL SEEING THAT?
03:19PM A. I DO.
03:19PM Q. AND THAT WAS FROM SOMEONE NAMED NELSON RHODES?

A. I DO, YES.
Q. AND THIS IS THE EMAIL THAT WE HAVE BEEN TALKING ABOUT FROM NELSON RHODES AT GSK?
A. YES.
Q. AND IF WE COULD PLEASE GO TO PAGE 2.
AND IF WE CAN SPLIT THE SCREEN, MS. HOLLIMAN, WITH EXHIBIT 291, PAGE 2.
DO YOU SEE ON THE LEFT SCREEN THE SECOND PAGE OF EXHIBIT 112, MS. HOLMES?
A. I'M SORRY, WHICH ONE?
Q. ON THE LEFT SIDE OF THE SCREEN --
A. YES.
Q. -- DO YOU SEE THE SECOND PAGE OF EXHIBIT 112?
A. I DO.
Q. OKAY. AND TO THE RIGHT IS THE SECOND PAGE OF EXHIBIT 291 AT PAGE 2?
A. YES.
Q. AND 291 IS THE DOCUMENT THAT GOES TO WALGREENS?
A. YES.
Q. OKAY. THERE'S A LOGO FOR GSK AT THE TOP LEFT OF 291.
DID YOU ADD THAT LOGO?
A. I ASSUME SO.
Q. AND DID YOU PROVIDE THE -- AND YOU PROVIDED THE DOCUMENT IN 291 TO WALGREENS?
A. I DID.

03:22PM Q. DID YOU RECEIVE ANY PERMISSION FROM GSK TO ADD THE LOGO?
03:22PM A. I DON'T KNOW.
03:22PM Q. AND YOU HAVE NO MEMORY OF RECEIVING ANY ORAL PERMISSION FROM GSK TO ADD THE LOGO?
03:22PM A. I DON'T.
03:22PM Q. AND YOU HAVE NO MEMORY OF ANY WRITTEN COMMUNICATION FROM GSK AUTHORIZING YOU TO ADD THE LOGO?
03:23PM A. I DON'T.
03:23PM Q. AND YOU DON'T HAVE A MEMORY OF TELLING ANYBODY FROM GSK THAT YOU HAD ALTERED THE DOCUMENT IN EXHIBIT 112?
03:23PM A. I'M NOT SURE. THERE WAS A GSK EXECUTIVE THAT CAME IN TO WORK WITH US WHO WAS IN ACTUAL COMMUNICATION WITH THEM.
03:23PM Q. BUT YOU DON'T HAVE A MEMORY OF HIM TELLING YOU TO AFFIX THE LOGO TO THIS AND DO WHAT YOU WILL TO IT?
03:23PM A. NO.
03:23PM Q. DID YOU TELL ANYBODY FROM GSK THAT YOU MIGHT BE PROVIDING EXCERPTS OF A METABOLIC STUDY REPORT TO INVESTORS?
03:23PM A. WE MIGHT HAVE.
03:23PM Q. BUT YOU DON'T HAVE A MEMORY OF IT?
03:23PM A. I'M NOT SURE.
03:23PM Q. IF YOU COMPARE EXHIBIT 112 AT PAGE 2 ON THE LEFT TO 291-2 ON THE RIGHT, YOU'LL SEE THAT THE DATES ON MAY 27TH TO 28TH, 2008 ARE NOT PRESENT ON THE DOCUMENT WITH THE GSK LOGO.
03:24PM DO YOU SEE THAT?
03:24PM A. I DO.

Q. DID YOU DELETE THOSE WORDS?

A. I DON'T KNOW.

Q. IS THE REASON THAT THOSE WORDS ARE DELETED IS BECAUSE IT MIGHT SUGGEST THE LIMITS OF GSK'S EVALUATION?

A. I DON'T THINK SO.

Q. YOU DON'T RECALL TESTIFYING ABOUT ADDING THE GSK LOGO DURING YOUR DIRECT EXAMINATION, DO YOU?

A. I DON'T THINK SO.

Q. AND THERANOS DID MORE THAN SIMPLY DELETE DATES HERE.

WHY DON'T -- CAN I DRAW YOUR ATTENTION, PLEASE, TO THE BULLETS?

A. YES.

Q. IF WE COULD ZOOM OUT, MS. HOLLIMAN, AND GO TO PAGE 3 OF 112.

DO YOU SEE IN 112 THERE'S A BULLET UNDER "GSK METABOLIC BIOMARKER LAB COMMENTS" THAT SAYS, "FINGER PRICK/BLOOD DRAW PROCEDURE WAS DIFFICULT (NEEDED LARGER LANCET AND BETTER SYRINGE SYSTEM)."

DO YOU SEE THAT LANGUAGE?

A. I DO.

Q. AND THAT COMMENT IS DELETED FROM THE DOCUMENT THAT GOES TO WALGREENS; ISN'T THAT RIGHT?

A. I DON'T KNOW. I HAVEN'T LOOKED AT IT, BUT -- BUT I TAKE YOUR WORD FOR IT.

Q. DID YOU MAKE THAT DELETION?

03:26PM A. I DON'T KNOW.

03:26PM Q. OKAY. IF WE COULD ZOOM OUT, MS. HOLLIMAN, SO WE MIGHT -- DO YOU SEE HOW ON THE 291 UNDER "GSK METABOLIC BIOMARKER LAB COMMENTS," THERE ARE THREE -- SIX BULLETS OR --

03:26PM A. I DO.

03:26PM Q. AND THE LAST ONE ENDS WITH "ASSAYS TOOK APPROXIMATELY ONE HOUR."

03:26PM A. YES.

03:26PM Q. AND THE COMMENT ABOUT THE FINGER PRICK BEING DIFFICULT IS NOT THERE; AM I RIGHT ABOUT THAT?

03:26PM A. YOU ARE.

03:26PM Q. AND YOU DON'T KNOW WHO AT THERANOS MADE THE CHANGE TO THESE DOCUMENTS?

03:26PM A. I DON'T.

03:26PM Q. AND DID YOU EVER TELL ANYONE AT THERANOS THAT WE CAN'T HAVE THE SLIGHTEST NEGATIVE COMMENT IN WHAT IS GOING OUT TO OUR PARTNERS?

03:26PM A. I DON'T THINK SO.

03:26PM Q. AM I RIGHT THAT THE MEMO THAT DR. RHODES SENT YOU WAS NEVER INTENDED FOR USE OUTSIDE OF GSK?

03:27PM A. I DON'T KNOW.

03:27PM Q. DIDN'T YOU UNDERSTAND THAT IT WAS A MEANS BY WHICH OTHER UNITS WITHIN GSK MIGHT HAVE SOME INFORMATION ABOUT THERANOS?

03:27PM A. I THINK THAT'S WHAT THE EVALUATION WAS FOR.

03:27PM Q. OKAY. LET'S LOOK AT THE EMAIL.

CERTIFICATE OF REPORTERS

WE, THE UNDERSIGNED OFFICIAL COURT REPORTERS OF THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA, 280 SOUTH FIRST STREET, SAN JOSE, CALIFORNIA, DO HEREBY CERTIFY:

THAT THE FOREGOING TRANSCRIPT, CERTIFICATE INCLUSIVE, IS A CORRECT TRANSCRIPT FROM THE RECORD OF PROCEEDINGS IN THE ABOVE-ENTITLED MATTER.

Irene Rodriguez

IRENE RODRIGUEZ, CSR, CRR
CERTIFICATE NUMBER 8076

Lee-Anne Shortridge

LEE-ANNE SHORTRIDGE, CSR, CRR
CERTIFICATE NUMBER 9595

DATED: NOVEMBER 30, 2021

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA,	)	CR-18-00258-EJD
PLAINTIFF,	)	SAN JOSE, CALIFORNIA
VS.	)	VOLUME 46
ELIZABETH A. HOLMES,	)	DECEMBER 16, 2021
DEFENDANT.	)	PAGES 8899 - 9110

TRANSCRIPT OF TRIAL PROCEEDINGS
BEFORE THE HONORABLE EDWARD J. DAVILA
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

FOR THE PLAINTIFF:
UNITED STATES ATTORNEY'S OFFICE
BY: JOHN C. BOSTIC
JEFFREY B. SCHENK
150 ALMADEN BOULEVARD, SUITE 900
SAN JOSE, CALIFORNIA 95113

BY: ROBERT S. LEACH
KELLY VOLKAR
1301 CLAY STREET, SUITE 340S
OAKLAND, CALIFORNIA 94612

(APPEARANCES CONTINUED ON THE NEXT PAGE.)

OFFICIAL COURT REPORTERS:
IRENE L. RODRIGUEZ, CSR, RMR, CRR
CERTIFICATE NUMBER 8074
LEE-ANNE SHORTRIDGE, CSR, CRR
CERTIFICATE NUMBER 9595

PROCEEDINGS RECORDED BY MECHANICAL STENOGRAPHY
TRANSCRIPT PRODUCED WITH COMPUTER

11:15AM THE USE OF THE PFIZER LOGO, LET'S TALK ABOUT THAT FOR A MOMENT.

THE DOCUMENT ON THE LEFT IS THE DOCUMENT THAT WAS SENT TO PFIZER. THE DOCUMENT ON THE RIGHT IS THE DOCUMENT THAT WAS SENT TO WALGREENS.

THE DOCUMENT ON THE LEFT IS THE DOCUMENT THAT WAS SENT TO SCHERING-PLOUGH. THE DOCUMENT ON THE RIGHT IS THE DOCUMENT THAT WAS SENT TO WALGREENS.

THE CONCLUSIONS IN THE SCHERING-PLOUGH DOCUMENT WERE ENHANCED. THE VERSION THAT WAS SENT TO SCHERING-PLOUGH IS THE ONE ON TOP.

11:16AM THE VERSION THAT WAS SENT TO WALGREENS HAD ADDITIONAL LANGUAGE IN IT, THAT THE THERANOS TESTS WERE MORE ACCURATE THAN THE CURRENT GOLD STANDARD REFERENCE. SO IT WASN'T JUST ADDING THE LOGO, IT WAS ACTUALLY ALSO DOCTORING OR ENHANCING THE CONCLUSIONS IN THE REPORT.

AND NOW LOOK AT WHAT MS. HOLMES SAID TO WALGREENS ABOUT THESE REPORTS. MS. HOLMES TOLD YOU ON THE STAND THAT SHE APPLIED THE LOGOS TO THOSE DOCUMENTS, I THINK FROM THAT TO SUGGEST I NEVER WOULD HAVE INTENDED -- THOUGHT I WAS DEFRAUDING ANYBODY IF I HAD GIVEN IT BACK TO THE PHARMA COMPANIES.

FIRST, IT CERTAINLY ISN'T ON THE PHARMA COMPANIES TO DISCOVER THAT, TO REPORT IT BACK TO THERANOS, BUT IT ALSO MISSES THE POINT.

LOOK AT WHAT USE MS. HOLMES IS MAKING OF THESE DOCUMENTS.

11:16AM SHE WRITES IN AN EMAIL TO WALGREENS, "ATTACHED PER OUR
11:16AM DISCUSSION PLEASE FIND THREE INDEPENDENT DUE DILIGENCE REPORTS
11:17AM ON THERANOS SYSTEMS ATTACHED TO THIS EMAIL. THESE REPORTS ARE
11:17AM FROM GLAXOSMITHKLINE, PFIZER, AND SCHERING-PLOUGH AFTER THEIR
11:17AM OWN TECHNICAL VALIDATION AND EXPERIENCE WITH THERANOS SYSTEMS
11:17AM IN THE FIELD."

11:17AM SHE WANTS WALGREENS, AND THEN THESE WERE ALSO SENT TO
11:17AM PETERSON AND MOSLEY, TO CONCLUDE THAT THEY ARE INDEPENDENT DUE
11:17AM DILIGENCE REPORTS, THAT THE PHARMA COMPANIES PREPARED THE
11:17AM REPORTS AFTER THEIR OWN TECHNICAL VALIDATION.

11:17AM DR. CULLEN TOLD YOU THAT FOR THE SCHERING-PLOUGH WORK, THE
11:17AM DEVICE WAS AT THERANOS; THAT THAT'S WHERE THE TESTING WAS DONE.
11:17AM SO NOT ONLY WERE THE CONCLUSIONS IN THE SCHERING-PLOUGH
11:17AM DOCUMENTS THERANOS'S, THEY COULD NOT HAVE BEEN
11:17AM SCHERING-PLOUGH'S, BECAUSE SCHERING-PLOUGH WASN'T THE ONE WHO
11:17AM DID THE WORK.

11:17AM PETERSON RECEIVED THE PFIZER DOCUMENT. AND YOU KNOW
11:18AM MOSLEY RECEIVED THE PFIZER DOCUMENT ALSO.

11:18AM THE USE OF THE MILITARY. THIS CHART -- I'M SORRY, USE OF
11:18AM THE MEDIA.

11:18AM THIS CHART SHOWS YOU SORT OF THE THREE RELEVANT FACTS
11:18AM ABOUT EACH OF THE ARTICLES, "THE WALL STREET JOURNAL" AND THE
11:18AM PARLOFF.

11:18AM AT THE TOP YOU SEE THERANOS EMAILING THE RAGO ARTICLE TO
11:18AM SHAREHOLDERS, AND THEN YOU SEE THE LOCATIONS AND EXHIBITS WHERE

CERTIFICATE OF REPORTERS

WE, THE UNDERSIGNED OFFICIAL COURT REPORTERS OF THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA, 280 SOUTH FIRST STREET, SAN JOSE, CALIFORNIA, DO HEREBY CERTIFY:

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IRENE RODRIGUEZ, CSR, CRR
CERTIFICATE NUMBER 8076

Lee-Anne Shortridge

LEE-ANNE SHORTRIDGE, CSR, CRR
CERTIFICATE NUMBER 9595

DATED: DECEMBER 16, 2021

Exhibit 2

To: Alex.Jung@Walgreens.com[]
Cc: Jay.Rosan@Walgreens.com[]; Sunny Balwani[sbalwani@theranos.com]
From: Elizabeth Holmes
Sent: Wed 4/14/2010 5:25:08 AM
Importance: Normal
Subject: RE: Follow Up from Walgreens
Received: Wed 4/14/2010 5:28:46 AM
Theranos Evaluation Summary_GSK.pdf
Pfizer_Theranos System Validation_Final Report.pdf
Theranos Multiplexed Panel Validation Report_Schering Plough.pdf

Dr. Jay, Alex,

As per our discussion, please find three independent due diligence reports on Theranos Systems attached to this email. These reports are from GlaxoSmithKline, Pfizer, and Schering Plough after their own technical validation and experience with Theranos Systems in the field. Please note that these documents are strictly confidential under our CDA.

We met today on the request for names of persons who could come to Theranos to assess the technical performance of the systems; we will give you a call tomorrow to follow up on this.

We have a powerpoint summary of how Theranos Systems compare to other technologies in the market. Before sending, we tried to compare our presentation to the spreadsheet you referenced that lists different point of care technologies on Google, but we could not find the document you talked about. Please do send this to us so that we can add any relevant information from it to the presentation.

With my best regards,
Elizabeth.

Excerpts from GSK Metabolic Study Report

Nelson Rhodes, Director GSK Metabolic Biomarker Laboratory
Surekha Gangakhedkar, Theranos Assay Systems Lead

Background information:
The Theranos system was evaluated at GSK to profile active GLP-1 and C-peptide values and these data were compare to "gold standard" ELISAs using frozen human plasma from study XXXXXXX. The key project objectives (found in the attached statement of work) were:

- To assess the performance of the Theranos System in measuring a multiplex for GLP-1 and c-peptide values (the "Cartridge Analytes") as compar es to the current gold standard ELISAs (which are not multiplexed).
    - Specifically, the study will assess Theranos' capabilities to detect points that the reference assays failed to accurately detect by running samples with C-peptide values in a standard range (ng/mL) and GLP-1 values between 0-3.2 pM
- To assess the functionality, specificity, reproducibility, accuracy, and precision of the Theranos System.
- Assess the Theranos data reporting and transfer functions

Thirty plasma samples (assayed in duplicate) were chosen based on historical GSK data for total GLP-1 levels from subjects given a mixed meal and two finger prick blood draws were performed. Five Theranos machines were used with active GLP-1 and C-peptide cartridges that required 20µL of plasma. MesoScale Discovery's (MSD) active and total GLP-1, Linco (Millipore) active GLP-1, and Linco (Millipore) C-peptide ELISAs were run as comparator assays.

GSK Metabolic Biomarker Lab comments:

- Data show good correlation
    - $r^2 = 0.90$ for GLP-1 (MSD vs. Theranos)
    - $r^2 = 0.96$ for C-peptide (Linco vs. Theranos)
- Inter-instrument precision (RLU average %CV = 11)
- Machines worked well
- Touch-screen interface was easy to use
- Cartridges were pretty straight forward (easy to handle and load)
- Assays took approximately 1 hour and 15 minutes per cartridge

Overall conclusions:

- The Theranos system eliminates the need for a lab and provided quality data
- The Metabolic Biomarker Lab has a favorable impression of the technology/system and recommends GSK clinical groups to work with Theranos

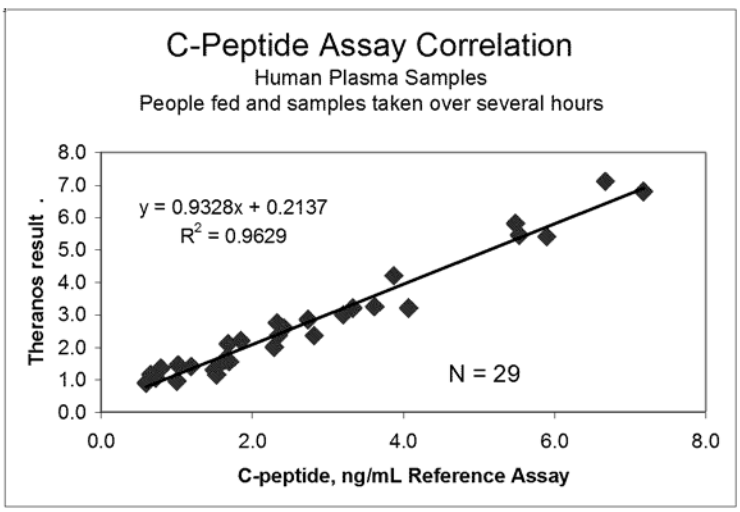
Data:

Study design

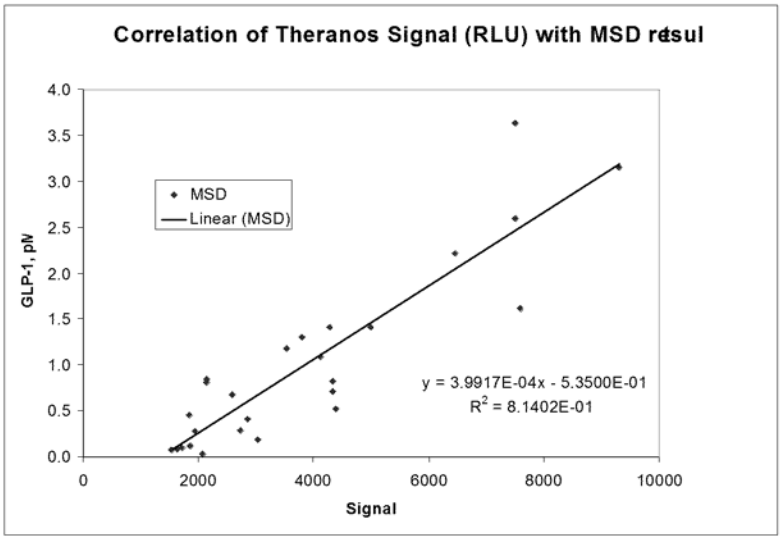
- Human subjects
- Food "challenge"
- Measure GLP-1 and C-Peptide multiplex over 5 time points
  - –LincoAssay
  - –MSD Assay
  - –Theranos Assay

C-Peptide Assay

Averaged results



Calibration to GSK matrix



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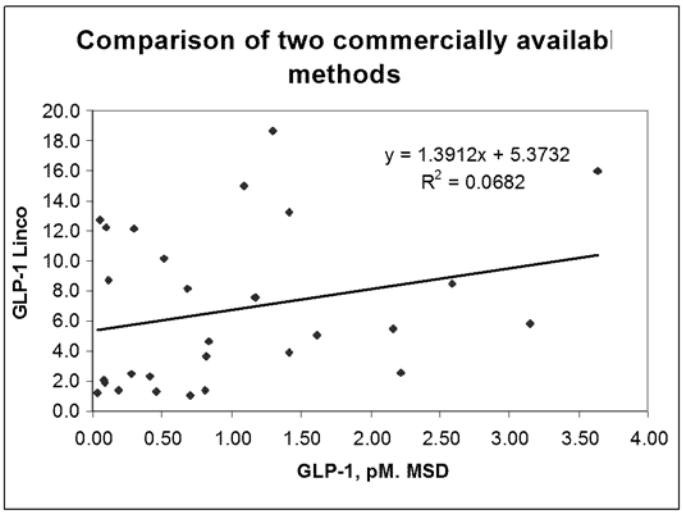
Lack of correlation of predicate methods



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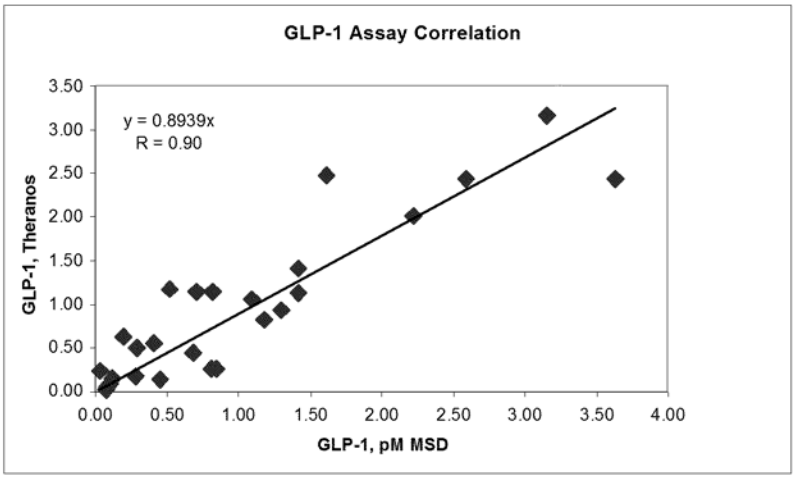
Assay correlation



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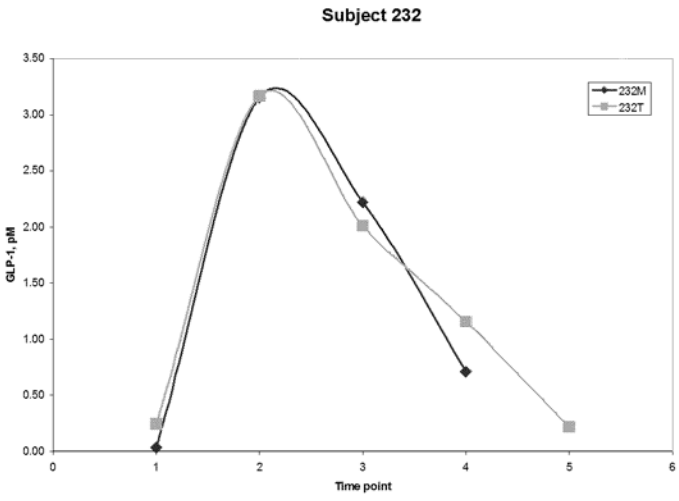
Subject 232



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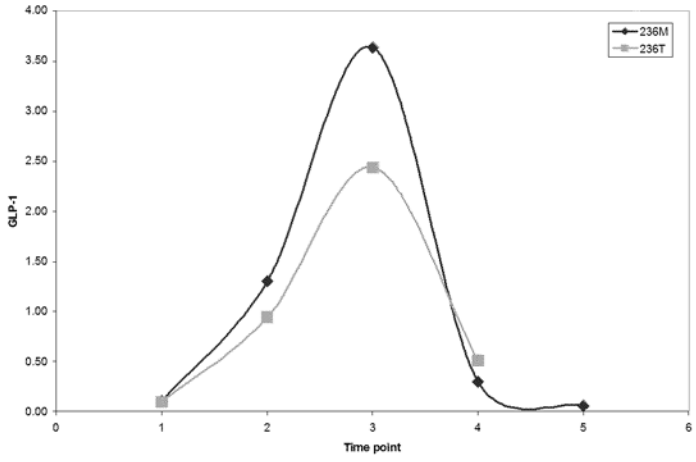
Subject 236



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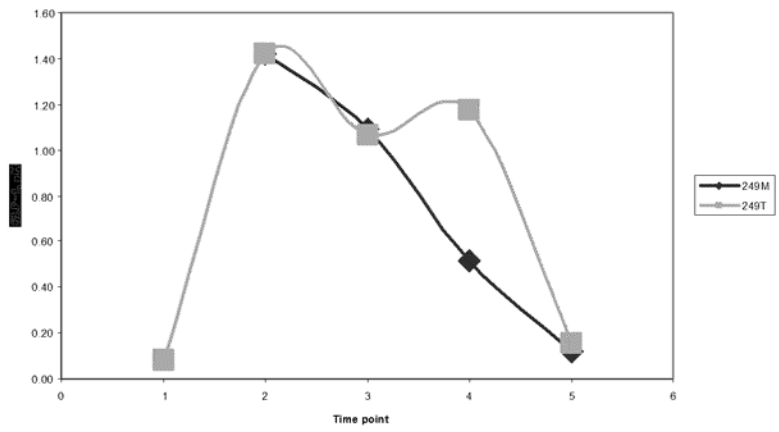
Subject 249



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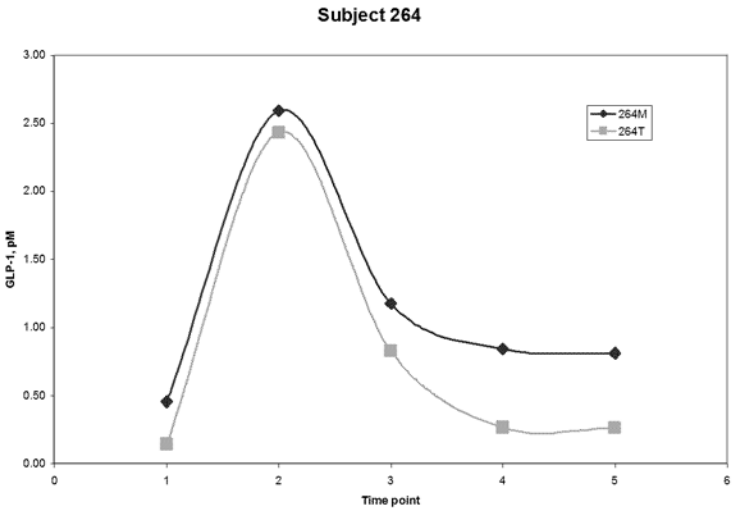
Subject 264



Summary Statistics GLP-1 Comparison

- TheranosLOD = 0.17 pM
- Dynamic range measured: 0-3.2 pM
- Mean = 0.9 pM (Th), 1.0 (MSD)

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Theranos Angiogenesis Study Report

Pfizer, Inc.

Document Outline:

- Introduction to Theranos
- Background on Theranos Studies
- Economic Impact of Theranos Systems to Pharma
- Angiogenesis Program Overview
  - Study design
- Theranos System Overview
  - Specifications
  - Theranos System Performance
- Theranos Field Study
  - Field Performance Overview
  - Trial Data
  - Evaluation of time course results from individual patients
  - Review of generated data, in aggregate by patient ID, sex, cancer type, treatment, etc.
  - Integrated patient information, including date and time of monitoring, medication received, self evaluation of overall health status of each patient and other clinical data in a comprehensive format
  - Assessment of the technical performance of the Theranos System
    - Data transmission % success and mode of transmission used
    - General performance information as logged via the Customer Care line
    - Assessment of patient compliance with protocol
  - Summary of patient and clinical staff assessment of the Theranos System and the Client Solutions team via end-of-study surveys
- Conclusions
  - General
  - Technical
  - Economic

Introduction to Theranos:

Accurately, rapidly, and effectively profiling the efficacy dynamics of a therapy in clinical studies is an unmet need that has long challenged the conventional blood testing infrastructure.

Theranos has demonstrated in clinical studies that more frequent longitudinal time-series measurements on fresh whole blood samples with a multiplexed platform that eliminates the noise (and inability to accurately characterize very broad dynamic ranges) of conventional tests is imperative to effectively characterizing physiological changes and the efficacy of any intervention.

Theranos' wirelessly integrated data analytical system allows for 'baseline' profiles of pathway dynamics to be created and updated automatically as data is generated in the field. If needed, analyte selection or frequency of sampling can be adjusted at any time during the study based on the data coming in.

In future studies within a given indication, the data analytical infrastructure can be used for predictive modeling wherein new patient data can be indexed against the stored baseline profiles for earlier reads on efficacy dynamics and dose-response.

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Background on Theranos Studies:

Every day gained in getting a new brand to market can be measured in millions of dollars.

Time is a major factor of cost of development of a new drug. For years the pharmaceutical industry has worked to drive every day possible out of the development process, and has reached a point where the physical limitations around the timelines for statistically significant data acquisition primarily determine the time to market.

Theranos Systems revolutionize those timeline constraints by enabling instant access to higher quality data and exponentially faster reads on efficacy and safety dynamics from the initiation of clinical trials. In doing so, Theranos is laying the foundation of a new growth model for pharma.

Theranos Systems radically impact revenues and growth on new and existing drugs in ways that were previously not possible:

- Faster approvals and studies - Immediate access to results enables immediate decision making and planning; early reads on efficacy dynamics and dose optimization for sub-populations through more comprehensive longitudinal PK/PD profiling
- Reimbursement and differentiation - Concrete reads on efficacy dynamics and visibility into mechanisms of action to optimize compounds dynamically
- Rapid access to multiple markets pre and post-approval - early reads on efficacy through trends in the change in rate of key markers allow for rapid label expansion
- Amelioration of safety concerns – more accurate reads on actual pathway dynamics enable rapid optimization where beneficial and delineation of patient sub-populations

Economic Impact of Theranos Studies to Pharma:

Based on Theranos' previous experience, predictive modeling and more comprehensive longitudinal profiling has resulted in the demonstration of meaningful dose-response and efficacy dynamics profiles in 6 month timeframes where the conventional infrastructure took two years and was still not able to generate hard correlations. An 18 month time-savings, not to mention the ability to gain insight into methods for optimization for label expansion, can conservatively be equated to hundreds of millions of dollars gained. With industry estimates at $1-3M a day for the value of each day gained in time to market, even 6 months saved ranges between $180M and $540M in return on investment.

Equally, once the infrastructure has been implemented, future studies are requiring about 25% fewer patients, reducing the patient costs, number of sites required, assay development, reagent screening, and infrastructure costs for shipping and processing samples through ambulatory point-of-care monitoring.

Overall savings on 6 month trials once the data analytical infrastructure has been established have averaged 50% of the cost of running an equivalent trial through the conventional infrastructure, further saving millions of dollars. As the data analytical engine evolves after the first 6 month study, costs are further reduced in each follow-on study, covering the cost of Theranos infrastructure and units many times over.

Ultimately though, the greatest economic return on investment lies in the ability to expand percentage market ownership through visibility into pathway dynamics that enables rapid characterization of responder populations in ways previously not possible. This capability enables

commercialization of 'targeted blockbusters' by redefining a company's historical success rate in realizing the target product profile of each drug once it hits the market.

Angiogenesis Program Overview:

The primary objective of the present program was to demonstrate the functionality of Theranos Systems in such a way that future studies could fully leverage the power of comprehensive longitudinal time-series profiling for rapid compound optimization and development.

For this program, Theranos was asked to develop multiplexed point-of-care assays for VEGF and PlGF for use in monitoring patient pharmacodynamic response to anti-angiogenesis therapies. Because the development of VEGFR2 in that multiplex was desirable as a tool for use in future studies, Theranos developed the assay and included it in the point-of-care multiplex.

In this program, Theranos validated not only functi onal equivalence, but superior performance specifications of the Theranos multiplex to each of the respective 'gold-standard' kits.

An Interim Report on Assay Development was submitted to Pfizer in Q2 '07 upon successful completion of assay development.

As planned for at the interim update meeting with Pfizer, the first patient began participating in the study in July of 2007. In order to fast-track the program timeline, Theranos contracted an independent site - Tennessee Oncology Center.

Enrollment of Sutent patients at this site was very slow; from the time patient screening began (early 2007) and after discussions with respective members of the Pfizer team, the protocol was revised several times to increase the frequency of monitoring but reduce the total number of patients and shorten the monitoring cycles per patient. Likewise, enrollment criteria were broadened to include patients on other therapies with whom trends in the relevant markers could also be profiled.

In doing so, statistical significance in meeting the study goals could still be ensured. Multiple IRB submissions were filed. Final IRB and Informed Consent Forms were included in two interim update reports sent to Pfizer.

Goals of Study:

1. Generate preliminary data on VEGF and PLGF trend s in cancer patients while assessing the use of the Theranos System in the hands of clinicians and patients.
2. Obtain feedback and recommendations from clinica l staff.
3. Assess the use of the Theranos System in the han ds of ambulatory patients at home.
4. Assess the Ambulatory Bioinformatics Communicati ons System[1] including the physician and patient web portals as well as the data reports generated.

Study design:
Patient screening began in January 2007, once the final site was selected, enrollment began. In July of 2007, the first patient was enrolled in the trial. This trial consisted of very ill late-stage (4th line) cancer patients with various tumor types receiving a variety of therapies at the Sarah

[1] The Ambulatory Bioinformatics Communication System (formerly known as ABCS) was rebranded as TheranOS, the Theranos Operating System.

Cannon Research Center at Tennessee Oncology (TNONC) in Nashville, Tennessee. The patients in the study typically resided in very remote locations across the eastern US. Almost all patients were not computer literate, and most were from low income families, unable to afford private telephone service.

The Theranos angiogenesis monitoring system was evaluated for clinical efficacy and as a means of more accurately and effectively monitoring cancer therapy and the progression of solid tumor cancers from a mechanism-of-action perspective. 32 patients were enrolled. Various cycles of therapies were monitored as well as physical changes in tumor size.

Four of the patients retracted consent to the study, three of them due to family problems and one due to mental and physical instability. Thus, Theranos increased the targeted enrollment number to ensure that the goal of demonstrating performance across significantly significant patient numbers would be met. That goal has now been achieved. To realize the goal, some patients had extended (60 day) monitoring periods.

Since Theranos has the ability to continue monitoring patients under the existing IRB and given the power of some of the correlations which are becoming apparent, Theranos may continue monitoring those patients for an extended period of time.

Enrollment was unpredictable and slow. All installations and shipments completed for this study were done on-demand with less than 24 hours. As part of the installation procedure, Theranos' client solutions team has performed at-home installations and pick-ups for many weak patients.

For each patient, a total of up to 14 time points w ere collected during the month-long analysis period, 3-4 time points taken at the clinic and the other 10-11 time points taken in-home. Both finger-stick and venous samples were taken during e ach clinic visit, while only finger-stick samples were run in-home. The venous draw samples were run on the Theranos System in the clinic at the time of the draw; these samples were also processed so that the plasma and/or serum was analyzed using a reference method.

Venous samples were processed using reference metho ds and provide an archive of 41 anti-coagulated plasma and serum samples which were frozen and have subsequently been analyzed at Theranos.

Theranos System Overview:

The Theranos System is comprised of consumer-orient ed readers, single-use cartridges containing assay chemistry and controls, and a data collection system that communicates through cellular networks with the instrument to pr ovide assay protocols and to compute and display results.

The steps required of a new patient are to 1) take the machine out of the box and 2) plug it into a power source. The touch-screen then walks each pati ent through the process of poking his/her finger, depositing blood into the cartridge, and pl acing the cartridge in the reader drawer. The instrument then processes the assays and sends the data through the cellular network in real-time to a secure web-portal.

Theranos Systems allow for quantitative, multiplexed longitudinal time-series measurements to map correlations between the rate of change of blood-borne markers over time to surrogate and clinical end-points.

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Specifications:

- Designed for at home use. Can also be used in phys ician's offices, ICU, and laboratories.
- Multiplexed measurement of biomarkers.
- Customizable for different/new assays on demand.
- Average 6 measurements per cartridge
- Serial measurements to comprehensively profile pha rmacodynamic response through trends
- Runs fresh whole blood, plasma or serum samples
- Finger-stick – small sample size
- Mix and match selection of analytes on demand.
- Wide measurement range
  - pg/mLl – mg/mL (1 billion fold)
- High sensitivity
  - 0.2 pg/mL (2 parts per 10-billion)
- Analyte Recovery: ~100 %
- System CV post-calibration (inter-intra reader, ca rtridge, and assay): < 10 %
- On-board chemistry controls
- Factory calibration (no user calibration)
- Wireless communication of results to appropriate u ser through cellular network
- Proprietary algorithms to interpret time trend res ults

The existence of a technology infrastructure for home, real-time blood monitoring allows collection of information which cannot be obtained using conventional blood testing scenarios:

- Small sample (finger-stick) + more frequent sampli ng of a small subset of analytes enables:
  - Identification of appropriate analytes (greatly he lped by more frequent sampling)
  - Earlier detection of efficacy and safety and acu te problems so intervention (for example, dose modification or change in drug type) can be more effective
  - Convenience of monitoring through-out a time-cours e before an event
- Higher sample integrity; real-time sample analysis on fresh whole blood on a standardized platform which can be deployed at any location (world-wide) eliminates assay inaccuracy associated with commercially available tests performed on samples which are "old" by the time they are analyzed.
  - Elimination of erroneous results (caused by analy te instability) and inherent errors in data and patient correlations (caused by processing data at various contract locations)

For this study, an instrument was deployed in the home of each patient; four others were installed at the Cancer Center.

Three assays were performed simultaneously in multi plex by the system on a finger-stick sample of fresh whole blood. The analytes were Vascular E ndothelial Growth Factor (VEGF), soluble VEGF receptor R2 (sVEGFR2, usually referred to as V EGFR2) and Placental Growth Factor (PLGF). Each assay was controlled using within-cartridge control measurements.

The system was calibrated at Theranos. Multiple car tridge lots were produced each with successively more clinically relevant specification s once samples were received from patients in the trial, as samples were not available during ass ay validation. Each lot was independently calibrated.

Traceability of calibration : Calibration is traced to authentic analytes diss olved at known concentrations in a plasma-like matrix. Calibratio n materials are prepared as mixed solutions of the three analytes. Assignment of calibrator conce ntrations is then made to values found for measurements of calibrators using reference assays.

System Performance Goals:

Assay	Reportable low pg/mL	Reportable high pg/mL Pr	ecision CV, %
VEGF	20	10,000	10
VEGFR2	150	15,000	10
PLGF	5	1,000	10

Assay ranges achieved:
The goals for each assay's dynamic range were achieved. Due to the inability to receive samples for calibration at the beginning of the studies, th e upper limit of calibration for VEGF was restricted to 3,000 pg/mL in the first cartridge lo ts, but then extended[2] to 10,000 pg/mL. For early cartridge lots the PLGF assay lower limit of sensit ivity was 50 pg/mL. Therefore, many early results for PLGF were out-of-range low ("OORL"). Lo ts produced after receiving samples for calibration have reportable ranges below 20 pg/mL.

[2] All three assays have a linear dose-responses extending far above the highest calibrator used.

Specificity:
The specificity of the assays depends on the pairs of antibodies chosen for each assay. In the first instance, we rely on the antibody vendor information. Selected pairs are known to have good specificity in ELISA assays. Key issues for these analytes are (1) the structural relationship of VEGF and (2) the fact that VEGF binds to sVEGFR2. We have shown that the Theranos assay system is not affected by the presence of VEGF and VEGFR2 and PLGF in the same samples. In many patients in this study, the drug Avastin is used. This drug is an antibody that binds to VEGF. It is obvious that ELISA assays for VEGF (an d perhaps VEGFR2) using antibody pairs are likely to be interfered with by Avastin. As documented below, Theranos assays for VEGF and VEGFR2 appear to function with minimal interference from Avastin. In contrast, the selected reference assay for VEGF is strongly interfered by Avastin.

Theranos System Performance:

Assay accuracy:
Accuracy has been evaluated by analysis of clinical samples. Two sets of samples have been used: (1) A set of 12 serum samples from cancer pat ients (obtained from a commercial vendor), (2) 41 archived serum and plasma samples from this study. Because Avastin was used to treat many of the patients in the TNONC study and this an tibody strongly interferes with the reference method, we used the commercially available samples for VEGF assay evaluation.

Twelve serum samples were assayed (singlicate) in t he Theranos system and in duplicate for the reference method with the following results:

VEGF: y (Theranos) = 0.785 x (reference) + 95.2; R ^2 =0.99. Range 96 – 1985 pg/mL. One sample was rejected from the analysis giving very h igh results in the Theranos system and low results in the reference assay. Based on the study data, it seems likely this patient was being treated with the drug Avastin, which interferes with the reference assay.

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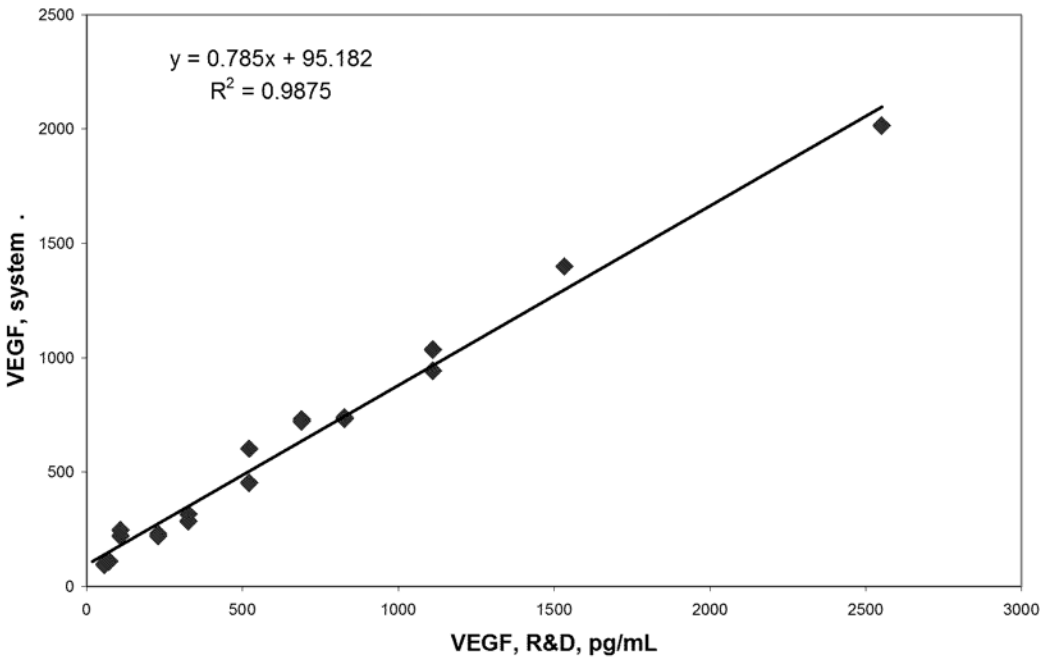
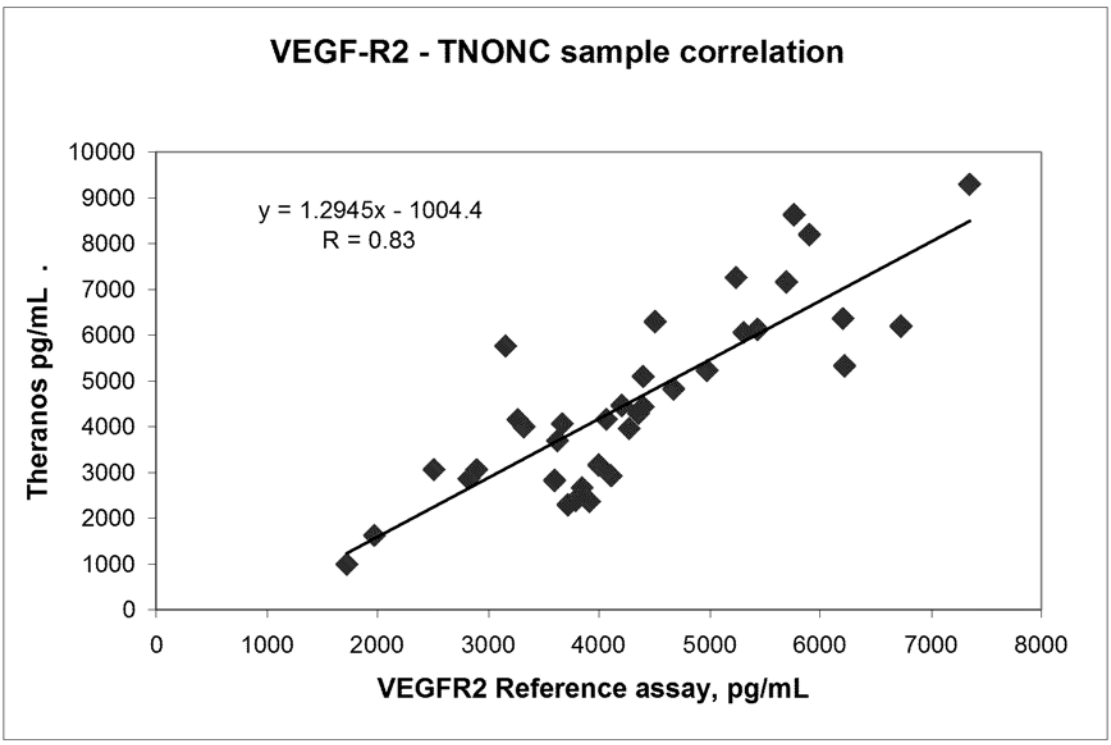
Single cartridge clinical results

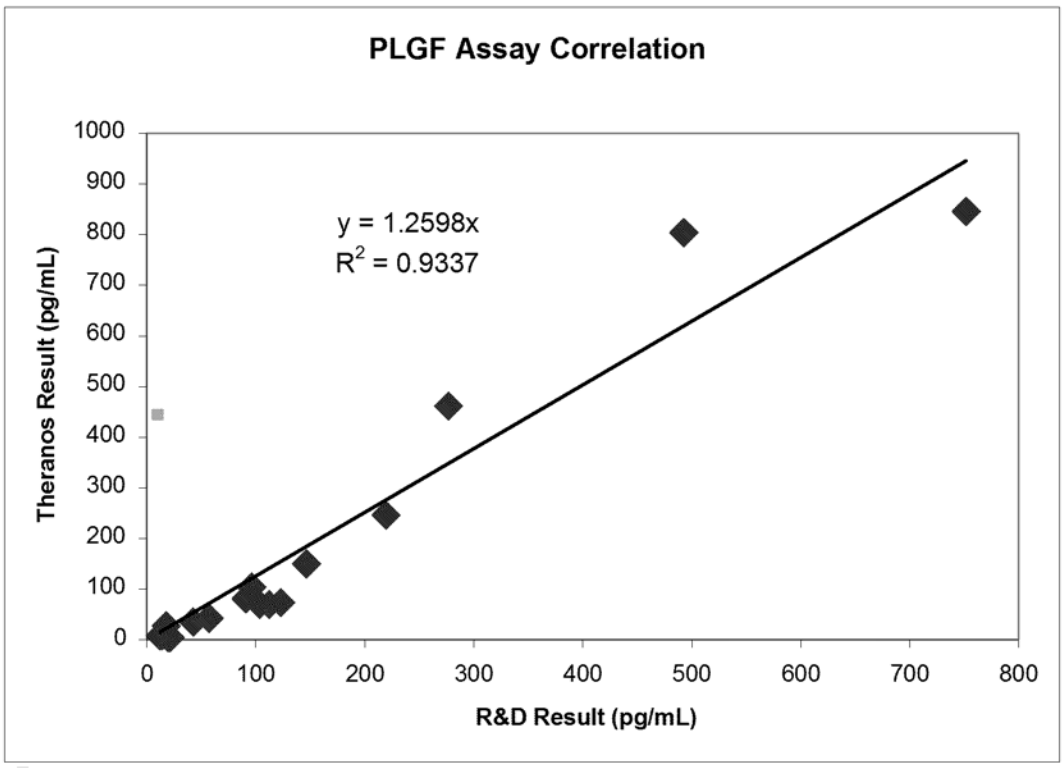


For VEGFR2, 39 TNONC samples were assayed in tripli cate in the Theranos system and duplicate for the reference method. The results we re: y (Theranos) = 1.29 x (reference) + 1004; R =0.83. Range 1015 – 9285 pg/mL.

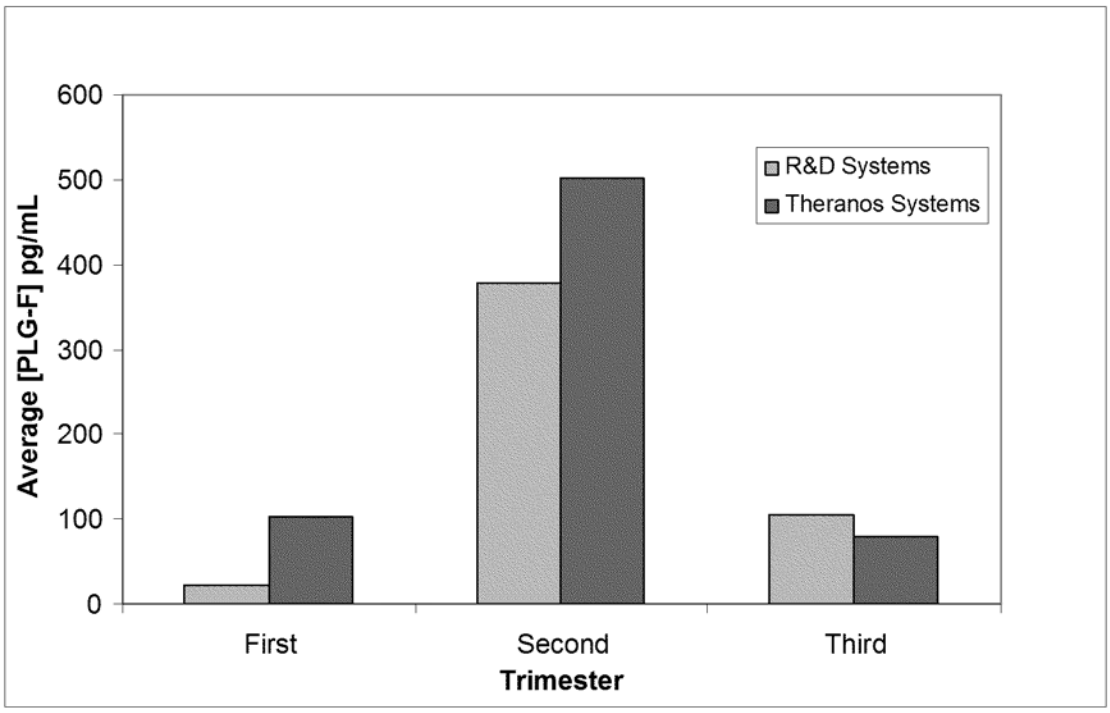


For the initial PLGF samples analyzed by Theranos in the field and with the reference method the results fell mostly in the undetectable range of bo th methods. Once the Theranos calibration was re-optimized, values became detectable from 5-17 pg/mL in the out-of-range-low venous samples sent to Theranos.

A significant correlation was achieved during valid ation on normal serum samples from twenty pregnant women assayed in quadruplicate. They were analyzed on both the Theranos system and the reference R&D Systems kit. The following re sults were obtained: y (Theranos) = 1.26*x (R&D Systems); R = 0.96. The average within sample CV for the Theranos results was 9%. One sample (shown in pink) below gave discrepant results.



When the results for patients were segregated by tr imester and averaged, the concordance shown below was found.



Effect of Avastin on the reference VEGF assay:
Comparison of reference and Theranos VEGF assay results for venous samples were not correlated. Many Theranos results were in the thousands of pg/mL where reference assay gave a low value. Since it was noted that many of the patients had been treated with Avastin which binds to VEGF, Theranos did a study of spike recovery for the reference method. VEGF (400 pg/mL) was added to each sample and the assay repeated. Results are shown below:

Avastin Present	VEGF average, pg/mL Ref	VEGF average, pg/mL Theranos
N	149	588
Y	136	8359

	VEGF spike recovery, %
N	66.5
Y	-1.3

It is evident that Avastin completely blocks the reference assay response. Presumably, Avastin binds at a site on VEGF close to or identical with that recognized by one of the antibodies used in the reference method. The reference assay thus responds only to free VEGF whereas the Theranos assay is not blocked and measures both Avastin-bound and free VEGF.

Assay precision:

Inter-Instrument Precision:
Venous samples from patients were run across four instruments.

Assay	Reportable low pg/mL	Reportable high pg/mL	Precision CV, %
VEGF	20	10,000	8.0
VEGFR2	150	15,000	7.3
PLGF	5	1,000	9.2

Precision in comparison to available reference meth ods was evaluated during calibration. Singlicate measurements from six instruments were u sed next to commercially available 'gold-standards'. Theranos adjusted the target range afte r obtaining clinical samples. Due to the superior performance characteristics of Theranos' a ssay next to commercial standards, obvious variances are seen where the reference methods report OORL.

Single lot calibration data:

Analyte	Range (pg/mL)	Average CV, %
VEGF (lot 3)	30 – 10,000	12.0
VEGF (lot 1)	30 – 3,000	10.0
VEGFR2 (lot 3)	1,000 – 10,000	4.8
VEGFR2 (lot 1)	50 – 800	17.6
PLGF (lot 3)	5 – 780	26.9
PLGF (lot 1)	50 – 800	9.1

Precision was also measured by analysis of the 41 a rchived clinical samples in assays and for VEGF 12 commercial samples.

Analyte	Range (pg/mL)	Average CV, %
VEGF	30 – 10,000	16.7
VEGF[3]	96 – 1985	5.7
VEGFR2	1,000 – 10,000	20.4
PLGF	5 – 780	28.7

Dilution linearity:

Data gathered during lot calibration.

VEGF, pg/mL	Recovery, %
10000	(100)
2970	102
990	95
297	105
100	109
30	105
10	101

[3] Commercial samples

VEGFR2, pg/mL	Recovery, %
10560	(100)
7920	92.9
5280	100.9
3960	104.8
2640	97.7
1320	100.8

PLGF, pg/mL	Recovery, %
780	100.0
312	87.6
156	102.8
47	106.3
16	92.4
5	99.4

For all assays, recovery was close to 100 % in the reportable range.

Limit of detection (LOD):
Data gathered during calibration. The LOD is defined at a 95 % confidence level.

Analyte	LOD, pg/mL
VEGF	< 20
VEGFR2	< 200
PLGF[4]	< 20

Theranos Field Study:

The system has been deployed to patient's homes and the TNONC study clinic and has downloaded protocols and uploaded data wirelessly. Some patients used direct telephonic communications (POTs modems) if they were worried a bout cell reception. Data for every patient has been profiled on a secure, Pfizer-specific server.

Field Performance Overview:

In this report we document results from:

- 27 patients (41% female and 59% male)
- 13 cancer types
- 38 Instruments
  - 27 instruments deployed to patients' homes

[4] Later stage cartridge lots

- 4 instruments deployed to the clinical site in Nas hville, TN
- 4 updated instruments to replace the readers at th e clinical site such that the latest design revolution is deployed at the site
- 3 were used to replace malfunctioning readers in t he field (2 at clinic - one with communication issue, one mechanical due to user error; 1 at patient's home with mechanical issues from shipping)

• 445 cartridges (approximately 1300 assay results)
- This number includes cartridges run in-house on ar chived plasma as well as results gathered in-field

Data acquisition has proven feasible in the home setting. There were instruments in the field operating in extreme temperature conditions (from very hot, no A/C to A/C turned to the maximum) as well as in very diverse locations (from RV's to log cabins in the middle of forests), in remote, difficult to reach areas where poor cellular reception is prevalent.

The instruments have been deployed across three states, including Kentucky, Pennsylvania and Tennessee. As mentioned, typical turnaround time for installation and patient at-home test was less than 24 hours without notice.

In monitoring this multiplex of analytes at far greater frequency than ever before, considerable patient-response variation can be seen across different sub-patient populations, therapies, and cancer types.

When we look at the average results from each patient and the variation seen for each patient, it is evident that the patients vary drastically:

	VEGF Avg., pg/mL	VEGFR2 Avg., pg/mL	PLGF Avg., pg/mL
Maximum	13,584	6,317	410
Minimum	47.5	368	37.3

By evaluating sample statistics such as these, one can identify patients who are anomalous and who may benefit from therapy modifica tion.

For example, of the 13 patients with colon cancer we see one subject with an average VEGF of 13,600 pg/mL and another with an average of 255 pg/mL whereas most of the patients had VEGF values quite closely clustered at 1000 - 5000 pg/mL. Similarly, we see some subjects who show very little variation in analyte values and others with wide variations presumably related to response (high or low) to therapy.

Trial Data:

The following raw trial data is included in the appended spreadsheet:

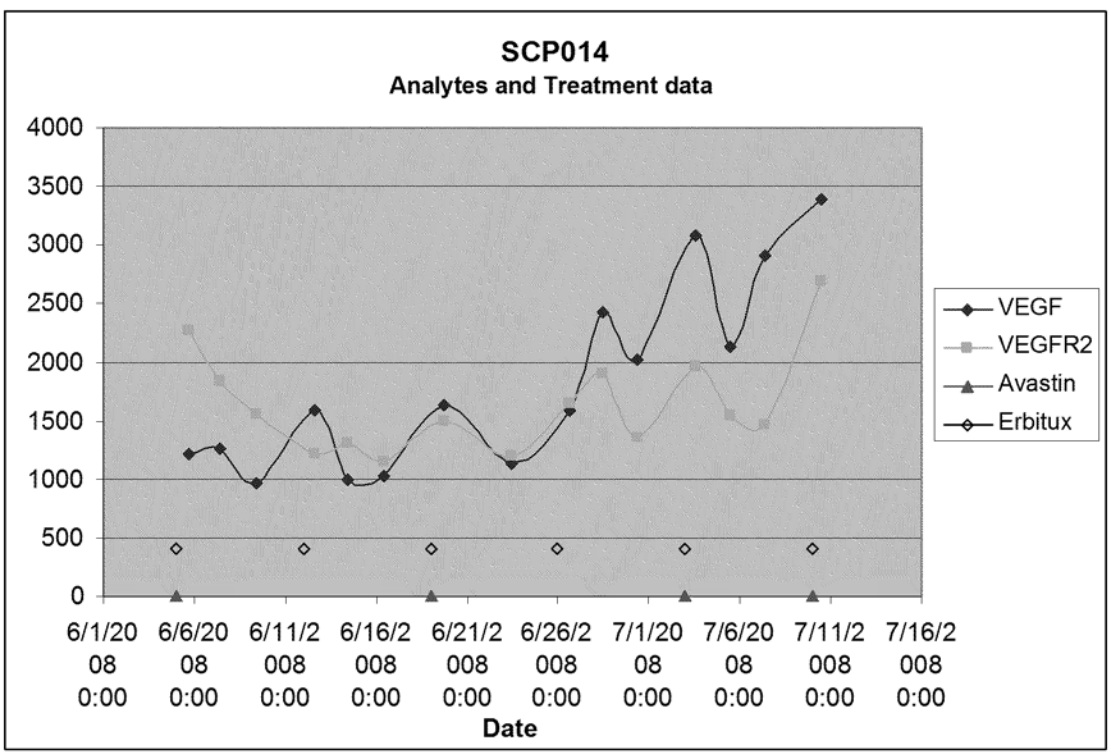
1. Clinic visit diagnostics (Patient characteristic s and Clinical assay results)
2. Clinic visit pivot table (clinical results prese nted as a customizable pivot table)
3. Patient aggregate data (Compliance data, Result averages and CVs by patient and averages by cancer type)
4. All field analyte data results (from the Therano s system presented by patient in a filtered table format [sort-able])
5. Treatment data (drugs used and dosage)

6. Individual end-of-study results (patient evaluat ion of system)
7. Compilation and summary of end-of-study survey r esults
8. Data transmission statistics

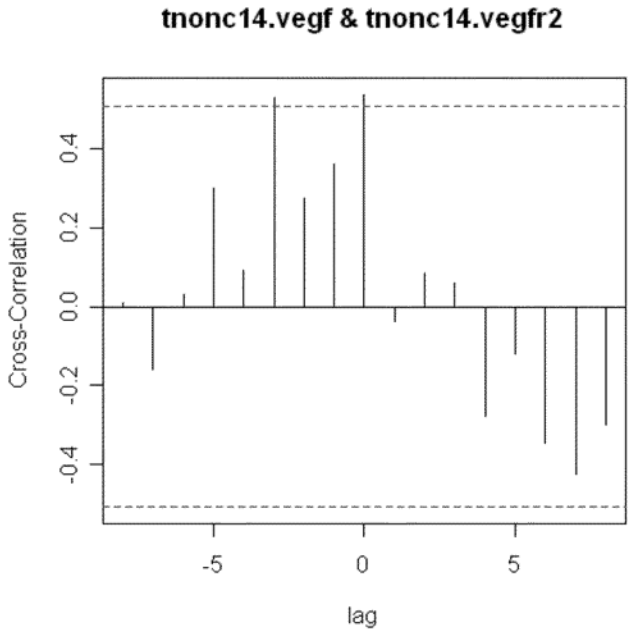
Evaluation of time course results from individual patients:

The study data demonstrates that in a larger, statistically controlled study, where the endpoint is directly proportional with patient outcome, e.g., a RECIST Score, a correlation between analyte dynamics and patient response to treatment would be generated.

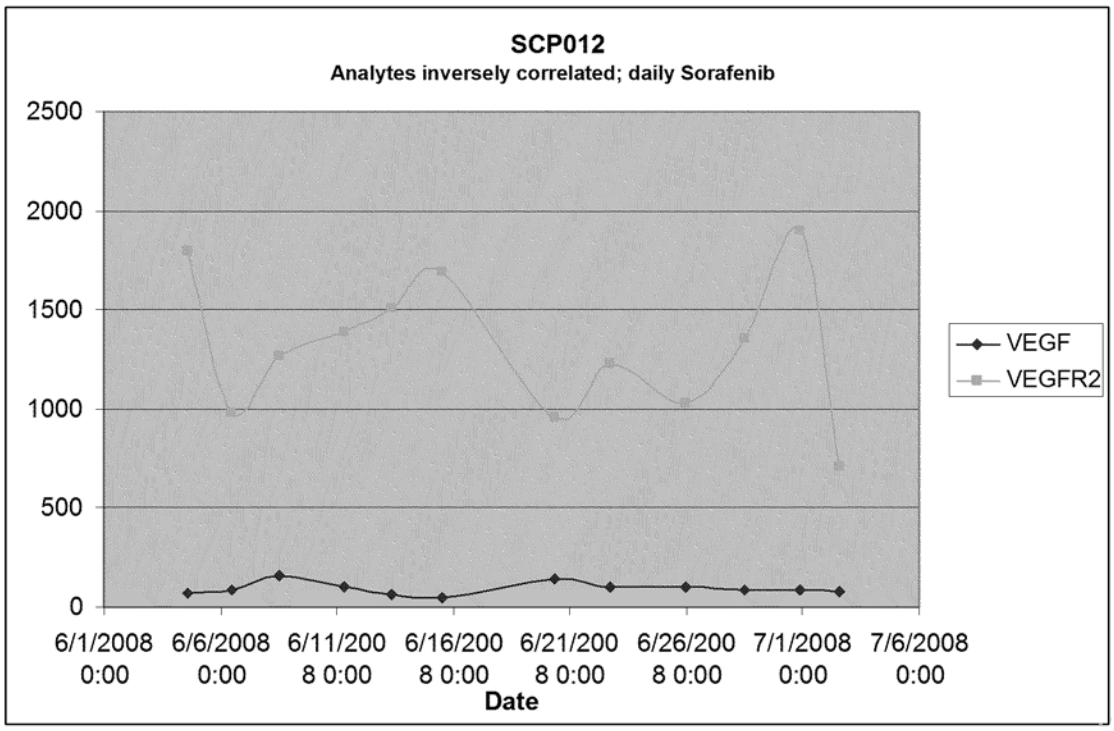
To showcase the ability to profile predictive correlations between treatment and response profiles, we selected data from two patients -- 14 and 12. Due to patient 14's clinic schedule (first figure below), we were able to collect data following multiple infusion dates, allowing limited statistical analysis to be performed that correlates analyte levels with treatment administration. The cross-correlation function (second figure below) looking at VEGF and VEGFR2 blood levels for patient 14 shows a positive correlation at a cadence of 3 data points. This coincides with the patient's weekly clinic visits during which the patient receives the Avastin infusions.

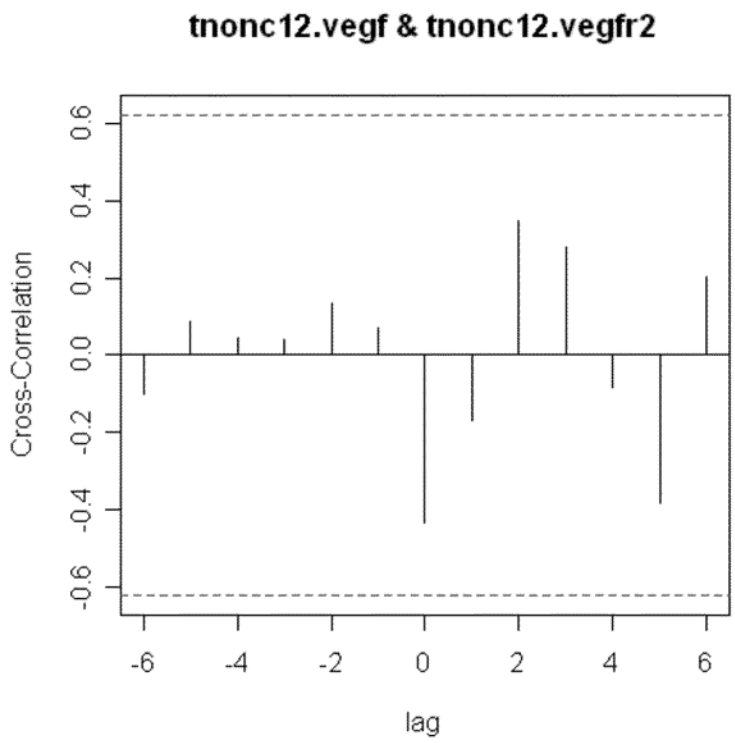


The change in rate of the parameters can be correlated to progress, seen again below in a correlation plot:



For patient 12 (first figure below), we observe an inverse correlation between VEGF and VEGFR2 blood levels. This suggests that the blood analytes behave differently with different drug treatments, pointing at distinct pathways of drug activity (second figure below).





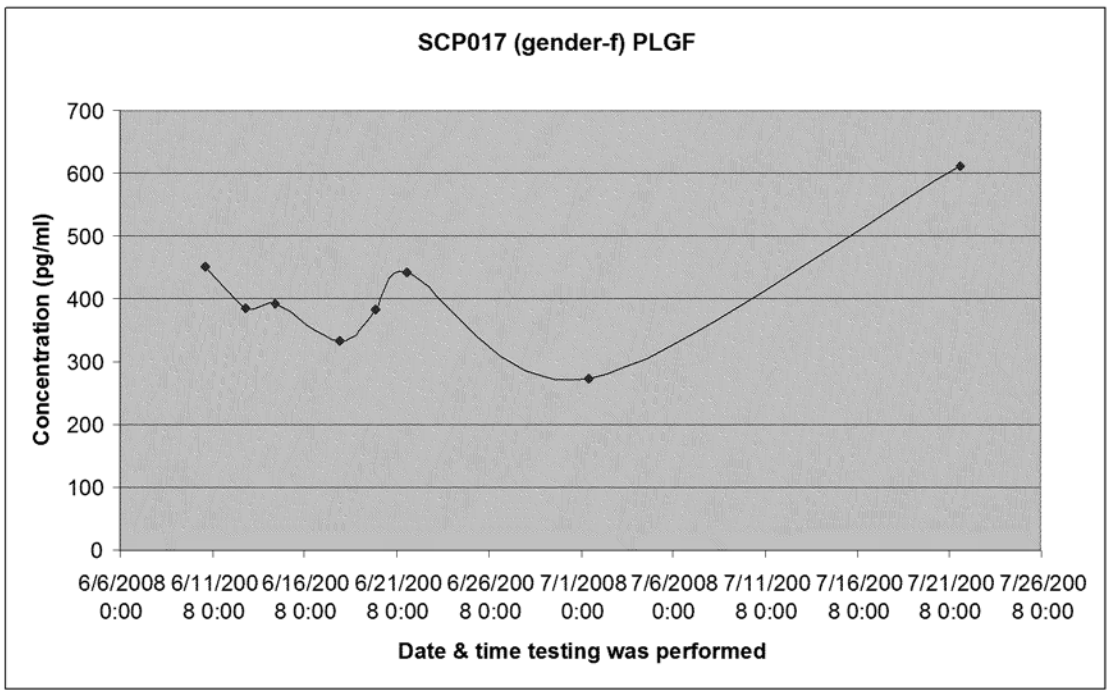
For most patients analyzed, the sample size and sample numbers did not provide sufficient statistical power to derive a statistically significant conclusion but some clinical endpoint measurements were accessible to correlate analyte vectors and their rates of change with time to the patient's progression and response to treatment.

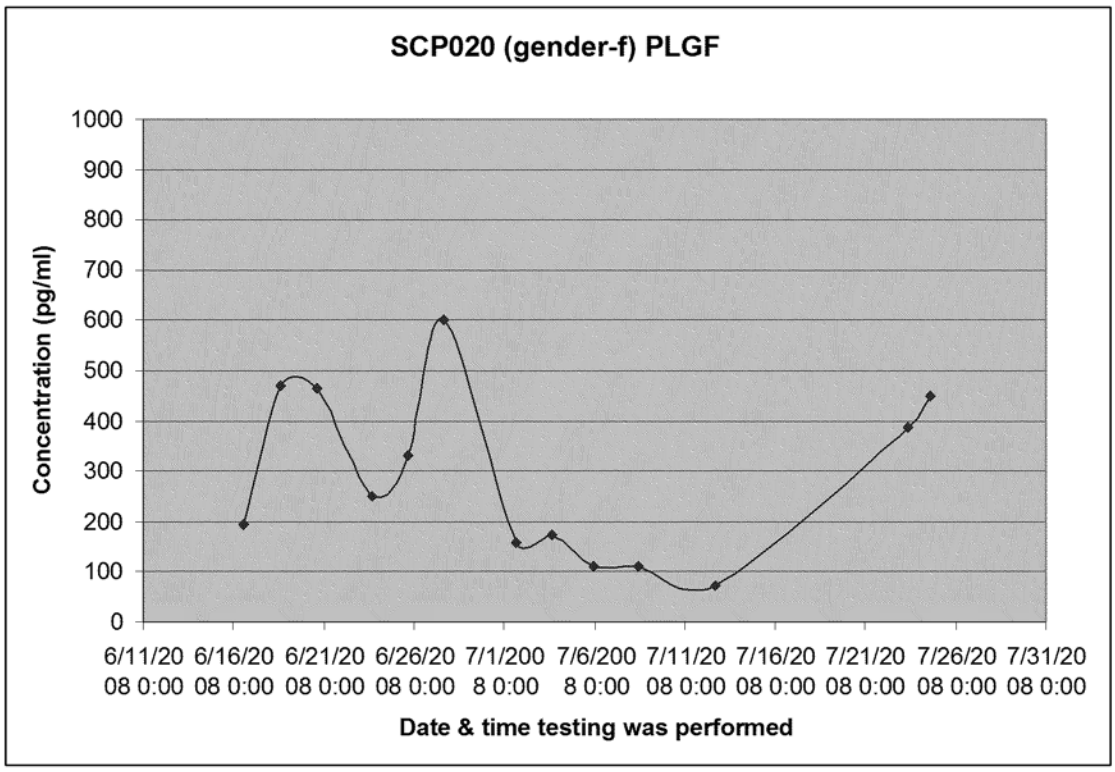
Patient average VEGF and VEGFR2 data by cancer type:

Patient ID	Cancer type	Main Treatment	Average VEGF (pg/ml)	Average VEGFR2 (pg/ml)
SCP001	Adenocarcinoma	Sutent	47.5	2592
SCP006	Breast Cancer	Avastin	2082	2662
SCP010	Breast Cancer	Avastin	2055	3040
SCP008	Breast Cancer	Sorafenib	98	1863
SCP021	Colorectal Cancer	Avastin	4677	3646
SCP027	Colorectal Cancer	Sorafenib	1093	4863
SCP029	Colorectal Cancer	Sorafenib	3612	5658
SCP003	Colorectal Cancer	Sutent	72	2798
SCP007	Colorectal Cancer	Avastin	3860	2350
SCP009	Colorectal Cancer	Avastin	1840	368
SCP022	Colorectal Cancer	Avastin	Patient dropped	N/A
SCP014	Colorectal Cancer	Avastin	1826	1634
SCP019	Colorectal Cancer	N/A	Patient dropped	N/A
SCP016	Colorectal Cancer	Avastin	3006	2143
SCP031	Colorectal Cancer	Avastin	13584	5463
SCP024	Colorectal Cancer	Sorafenib	255	1540
SCP028	Colorectal Cancer	Sorafenib	1274	6317
SCP023	Esophageal Cancer	Avastin	3145	2260
SCP030	Gastrointestinal Stromal Tumor	Sutent	889	2424
SCP012	Liver Cancer	Sorafenib	96	1253
SCP017	Lung Cancer	Avastin	3947	2111
SCP025	Melanoma	Avastin	5399	3294
SCP002	Neuroendocrine carcinoma	N/A	Patient dropped	N/A
SCP026	Ovarian Cancer	Sorafenib	Patient dropped	N/A
SCP020	Renal Cell Carcinoma	Sutent	368	883
SCP004	Renal Cell Carcinoma	Avastin	2316	1057
SCP011	Renal Cell Carcinoma	Avastin	3159	1911
SCP013	Renal Cell Carcinoma	Avastin	3908	770
SCP015	Renal Cell Carcinoma	Avastin	3031	1068
SCP018	Tongue Cancer	Avastin	1457	3074
SCP005	Unknown Primary	Avastin	3099	2980

As referenced, patients #2, #19, #22, #26 dropped out of the study for various reasons; therefore average values are not statistically significant for them.

For the patients in whom PLGF is consistently detectable we selected plots as shown below.





Patient monitoring times and quality of life by gender:

			Time of day when home monitoring was performed	Quality of life (as measured by on-screen survey)
Patient ID	**Cancer type**	**Gender (on average)* (on ave**		**rage)***
SCP001	Adenocarcinoma	f	Morning	N/A (Survey was not yet deployed)
SCP006	Breast Cancer	f	Afternoon	7
SCP010	Breast Cancer	f	Evening	8
SCP008	Breast Cancer	f	Late Evening	7
SCP021	Colorectal Cancer	f	Noon-afternoon	8
SCP027	Colorectal Cancer	f	Afternoon	10
SCP029	Colorectal Cancer	f	Afternoon-Evening	not yet available
SCP003	Colorectal Cancer	f	Morning	N/A (Survey was not yet deployed)
SCP017	Lung Cancer	f	Evening	9
SCP026	Ovarian Cancer	f	N/A	N/A
SCP020	Renal Cell Carcinoma	f	Afternoon	6
SCP005	Unknown Primary	f	Afternoon	9

SCP007	Colorectal Cancer	m	Evening	7
SCP009	Colorectal Cancer	m	Late Evening	7
SCP022	Colorectal Cancer	m	N/A	8
SCP014	Colorectal Cancer	m	Morning	7
SCP019	Colorectal Cancer	m	N/A	N/A
SCP016	Colorectal Cancer	m	Evening	8
SCP031	Colorectal Cancer	m	Afternoon	not yet available
SCP024	Colorectal Cancer	m	Afternoon	9
SCP028	Colorectal Cancer	m	Evening	not yet available
SCP023	Esophageal Cancer	m	Morning	8
SCP030	Gastrointestinal Stromal Tumor m		Morning	not yet available
SCP012	Liver Cancer	m	Afternoon	10
SCP025	Melanoma	m	Morning	9
SCP002	Neuroendocrine carcinoma m		N/A	N/A
SCP004	Renal Cell Carcinoma	m	Noon-afternoon	10
SCP011	Renal Cell Carcinoma	m	Morning	9
SCP013	Renal Cell Carcinoma	m	Evening	10
SCP015	Renal Cell Carcinoma	m	Evening	7
SCP018	Tongue Cancer	m	Afternoon	5
* Actual time for each test point and diurnal variations of quality of life can be found online				

Patient compliance with optional on-screen questionnaire was approximately 86% (this number was calculated before the end of the study, therefore final compliance figures may change).

Patient clinical visit data by age:

Patient ID	Race	Smoking Status	Alcohol Consumption	Age	Weight (pounds)
SCP029	Caucasian	does not smoke now, positive history	None	36	179
SCP010	Caucasian	never smoked	monthly or less	45	165
SCP018	Caucasian	Smoke daily	None	45	181
SCP007	Caucasian	never smoked	None	46	213
SCP008	Caucasian	smoke occasionally	None	46	180
SCP002	Caucasian	never smoked	monthly or less	49	194
SCP016	Caucasian	smoke occasionally	monthly or less	49	167
SCP012	Caucasian	does not smoke now, positive history	None	53	190
SCP015	Caucasian	does not smoke now, positive history	None	53	174
SCP028	Caucasian	smoke occasionally	None	57	262
SCP001	Caucasian	does not smoke now, positive history	None	61	172
SCP027	African American	never smoked	None	62	167
SCP009	Caucasian	never smoked	None	63	221
SCP011	Caucasian	does not smoke now, positive history	monthly or less	63	305
SCP024	Caucasian	infrequent attempts (never developed a habit)	Every day	64	200
SCP023	Caucasian	never smoked	Every day	65	252
SCP005	Caucasian	does not smoke now, positive history	monthly or less	66	160
SCP021	Caucasian	smoke occasionally	monthly or less	66	198
SCP006	Caucasian	never smoked	monthly or less	68	163
SCP017	Caucasian	does not smoke now, positive history	Every day	69	112
SCP013	Caucasian	never smoked	monthly or less	71	230
SCP020	Caucasian	never smoked	None	72	101
SCP026	Caucasian	never smoked	None	73	132
SCP031	Caucasian	does not smoke now, positive history	None	73	134.5
SCP025	Caucasian	does not smoke now, positive history	None	77	184
SCP014	Caucasian	does not smoke now, positive history	monthly or less	78	217.5
SCP022	African American	never smoked	None	82	178
SCP030	Caucasian	never smoked	None	83	182

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Sample of patient clinical blood work by patient ID:

Patient ID	Avg. % Lymphocytes	Avg. Heart Rate	Avg. Total Bilirubin	Avg. Systolic BP	Avg. RBC
SCP001	33.4	67.7	0.7	129.3	3.2
SCP002	34.1	55.0	0.3	161.0	4.3
SCP004	27.8	64.7	0.5	144.7	3.2
SCP005	36.4	75.0	0.2	127.5	3.9
SCP006	29.5	100.7	0.3	112.7	4.3
SCP007	24.0	73.0	0.3	131.3	4.4
SCP008	23.7	84.0	0.4	124.0	5.1
SCP009	25.0	71.5	0.7	133.0	4.5
SCP010	45.3	74.3	0.9	137.8	4.5
SCP011	28.6	82.0	0.6	135.0	4.8
SCP012	28.3	75.5	0.7	122.0	4.0
SCP013	31.1	72.0	0.7	137.0	4.2
SCP014	40.2	81.5	0.4	125.3	4.0
SCP015	35.4	78.3	0.3	147.0	5.0
SCP016	18.0	75.3	0.3	131.3	4.9
SCP017	20.7	89.3	0.4	114.0	4.2
SCP018	23.4	70.0	0.3	133.0	4.8
SCP020	17.9	60.7	0.4	146.0	3.7
SCP021	36.5	91.0	0.4	130.0	4.8
SCP022	23.5	93.5	0.7	123.0	4.0
SCP023	26.3	107.7	0.7	119.7	4.7
SCP024	18.8	83.0	0.7	139.0	3.7
SCP025	33.5	94.0	0.3	143.0	5.2
SCP026	34.6	110.0	0.4	125.0	3.7
SCP027	9.5	70.0	0.7	119.0	3.7
SCP028	21.2	98.0	0.8	125.7	5.2
SCP029	32.6	90.5	0.6	122.8	5.1
SCP030	42.3	72.0	0.4	137.0	3.7
SCP031	16.7	70.0	0.4	145.0	4.3

All individual patient data was profiled as it was generated on the Pfizer-specific secure portal at www.theranos.com; raw data can also be found in the attached excel spreadsheet.

Server and Data Transmission

Approximately 361 cartridge results and 203 optional home surveys from the field were successfully transmitted to the Theranos servers. There were less than 5% transmission errors that required the readers to either retry sending the data or wait until they had a better connection to send the data. All data gathered in the field was transmitted to the Theranos servers. For the first two patients, on-screen surveys were not available. The number of surveys received is smaller than the number of cartridge runs due to the above as well as patients filling only one survey for each of their clinic visits (even though they ran two cartridges per visit). Once surveys

became available, each cartridge run also asked the user to complete an optional quality of life survey and compliance was very good.

Data distribution by transmission pathway to date		
Direct Internet Connection	Wireless-GSM	Traditional Phone line
5.6 %	90.7%	3.7 %

The only problem encountered with using GSM wireless phone technology was poor signal. The main reasons for poor cellular reception were: dense foliage, metal roofs and poor signal quality due to remote location. In one location (Stewart, TN), there was no cellular coverage at all; therefore the reader used the standard telephone line in order to connect to our servers and report data as it was gathered. All of this patient's logs were received by Theranos servers. In future studies, multiple network providers would be contracted for these areas.

Overall performance of the Theranos System based on Customer Care log:

The customer care line was available to patients 24 hours a day 7 days a week over the course of the entire study (July 07 to October 08). All calls were addressed professionally and all issues were resolved quickly, taking care to minimize the impact on patients and clinical staff.

The types of calls for which patients used the Customer Care line:

- Patient running low on supplies – the solution was to simply ship more of the needed supplies with overnight delivery to make sure patient had enough for the upcoming home tests.
- Patient not knowing how to turn machine on – the solution was to advise the patient over the phone on the procedures outlined in the setup sheet they received and to make sure they have the instrument up and running.
- Patient calling about scheduling an instrument pickup – solution was to schedule one of our representatives to pick up the machine or alternatively to have FedEx pick up the reader if patient was able to place it in the shipping container themselves.
- Patient called about blood transfer question – the solution was to advise the patient to leave the blood transfer device on a flat surface. If this solution was not sufficient, a new batch was shipped to make sure no capillary manufacturer defects were at fault.
- Patient called about instrument not recognizing cartridge – the solution was to ask patient to re-try and call back if problem persisted. The suspicion was that due to poor cellular signal the reader was unable to communicate, and by re-trying it would perform appropriately. There were no subsequent calls from patient.
- Patient called about instrument not being ready due to temperature – the solution was to ask patient to move reader away from A/C units and possible air currents. Patients had moved readers from initial installation location (one moved it to his RV, another into a really hot room) and the temperature extremes affected the readers' ability to maintain desired temperature. The Theranos readers are engineered to control temperature to eliminate variability associated with conventional assays.

The majority of systems deployed in the field performed their duties throughout the entire length of the patient monitoring schedule. One instrument had mechanical issues due to being misused; this happened during new personnel training at TNONC. The instrument was promptly replaced with a new instrument. Another failure occurred due to the instrument being damaged in shipping.

Although it performed its functions properly for the majority of the patient's schedule it eventually malfunctioned and was also promptly (~24 hours) replaced. Yet another issue was related to the cellular carrier not identifying the instrument. To expedite the process and assure that the clinic was adequately supplied it was decided to replace that instrument with one that was known to work. The problem was later resolved off-line.

Patient Compliance with protocol:

It is hard to estimate the patient compliance with the exact protocol due to the factors out of Theranos' control. In many instances patients re-scheduled their clinic visits and the new appointments were not communicated to us. At the onset of each patient's home monitoring they were provided with a tentative schedule which in many cases changed due to patient's need to travel or inability to keep scheduled appointments. With this in mind, we estimate that patient compliance with protocol was still very good, at approximately 96 % (measured as 80-120% of expected testing completed and received). Given the missing information, a much more accurate derivation would be possible.

Theranos System Assessment by Patients and Clinical Staff:

Patient end of study surveys were sent out to all participants. To date, 17 responses were collected from patients.

Summary of patients' assessment of the Theranos system:

- 88% of patients surveyed found the Theranos System easy to use; no patients found it "very hard" to use.
- 76% of patients found the written instructions to be very informative, with clear directions; 12% did not read instructions
- 91% of patients scored the training given by their Theranos representative either a 9 or 10 (10 being very good training)
- 76% of patients found the Theranos System takes li ttle time to use (scores between 1 and 4 were tallied, with 1 = very little time and 10 = a lot of time)
- 100% of patients found the optional touch screen s urvey on the Theranos System easy to use, giving scores of either 8, 9 or 10 (10 = easy to use, 1 = hard to use).
- On a scale of 10 to 1 (10 = least painful, 1 = mos t painful), only one patient gave the blood drawing experience a score of less than 6. 59% felt almost no pain, scoring either a 9 or 10.
- 100% of the patients that responded to the survey gave Theranos Customer Support an excellent or very good rating
- For the majority of patients, the Theranos System worked very well. The major ways of solving the questions patients had were figuring it out on their own or calling the Theranos Customer Care line.
- In the follow-up survey, 100% of patients that res ponded said they received excellent or very good technical support over the duration of the study.
- Most patients said they prefer monitoring from hom e (scored 8 through 10) using the Theranos System; 25% were indecisive (scored 4 to 6) when asked whether they prefer going to the clinic or using the Theranos System; only two patients would rather monitor at the clinic.

From the interactions with clinical staff at Tennessee Oncology, the system was:
1. well received and

2. the client solutions team made a very positive impact on the clinical staff and patients through promptitude and professionalism.

Conclusions:

General:

1. The Theranos System performed with superior perf ormance to reference assays while running in a complex ambulatory environment.
2. The existing Theranos support infrastructure ena bles on-demand home installation and patient training in extremely rural areas.
3. Patients preferred ambulatory monitoring to clin ic visits and liked using the Theranos System.
4. Non-computer literate patients had no issues usi ng the Theranos System.

Technical:

5. Inter-system accuracy is excellent and was demon strated on a platform with superior performance specifications to reference methods.
6. Calibrations were updated with access to samples from the trial.
7. Good correlations were seen to various commercia lly available gold-standards.
8. Avastin does not block the Theranos assay.
9. The Theranos System can measure VEGF both free a nd bound to VEGFR2 and Avastin to better quantify dose-response.

Economic:

10. This 15 month study demonstrated the robust fun ctionality of Theranos Systems. With this validation data, the technology can be applied to significantly cut costs and bring compounds to market faster:

11. More frequent sampling enabled better character ization of longitudinal time-series profiles of angiogenesis protein panels. More accurate insight of the change in rate of those panels over time enables significantly faster and earlier reads on efficacy dynamics.
    a. See efficacy dynamics trends and correlation to end-points in patient time-course profiles on the Pfizer web-portal at www.theranos.com.
12. Response profiles were seen in this study over 30 day intervals. Historically, these types of correlations have taken up to a couple years to demonstrate, or in some cases, were previously not demonstrable. This time gained facilitates rapid data generation for additions to a compendia and rapid label expansion of existing drugs. Equally, this approach can be used to fast-track approvals of key compounds and at the same time better optimize those compounds with better visibility to achieve the target product profiles.
    a. One of Theranos' pharma partners is publishing a report which estimates the increased time to market is valued at $1M per day – making every month quite substantial.
13. Through Theranos Systems, Pfizer will be able to reduce the number of sites, eliminate shipping costs for samples, processing costs, and analytical costs. Based on historical data, implementation of these systems will enable Pfizer to achieve ~50% cost savings over current study spending (previously demonstrated to be $15M of a $30M study budget). Equally, through better insight into pathway dynamics, Theranos is demonstrating the ability to reduce the number of patients required to show statistical significance in future studies by 30-50%.

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Schering Corporation
Schering Plough Research Institure
Assay Development Report
Theranos Systems Multiplexed Human IL-6, Human TNF-α, Human CRP (hs)

Contents

1. Introduction

The Theranos Assay System is a fully automated means for measuring concentrations of analytes (biomarkers, drugs) using immunoassay methodology. The system is comprised of instruments, single-use cartridges and a wireless communications link that conveys protocol information to the instruments from a Theranos Server and relays assay data to the Server for interpretation and distribution. Blood, plasma serum and control materials may be analyzed by the System. Calibration is performed at Theranos on a cartridge-lot-specific basis.

The System accepts a metered sample (15uL) from a proprietary sampling device or a pipette, dilutes it automatically to levels appropriate to each assay then executes an automated ELISA assay protocol. The protocol is selected from a set of released protocols available on the Theranos Server and identified by reading a bar code on each cartridge. The bar code is also linked to an assay lot-specific calibration algorithm. Assays are complete in about one hour.

Assays are typically grouped (multiplexed) in particular cartridges designed to monitor specific disease and therapeutic processes. For example, a cartridge designed to monitor acute and inflammatory processes measures IL-6, TNF- α and CRP. Customer is interested in use of the Theranos System and has sponsored a validation exercise at Theranos focused on the inflammatory marker cartridge.

In this exercise, many instruments (60) and three lots of cartridges were used for validation of system level performance: inter-intra device, cartridge, and assay performance.

2. Storage and Use

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Theranos cartridges should be stored in the original unopened packaging in an upright position at 4°C. Theranos instruments require no user maintenance or calibration. User prompts are provided on a screen which is part of the instrument.

3. Calibration

IL-6 and TNF-α assay calibration utilize recombinant analytes expressed in human-cell lines as calibration materials. These are reportedly more stable than recombinant analytes made in bacteria and more similar to the naturally occurring analytes. The CRP assay is calibrated with a human plasma-derived analyte. Theranos Systems assays recognize "natural", recombinant, and human-cell line expressed recombinant forms of IL-6 and TNF-α. Each lot of Theranos Cartridges is individually calibrated, the calibration equation is linked to the cartridge barcode and results are automatically computed on the Theranos data server. For this validation study, three cartridge lots were produced and calibrated.

NIBSC WHO Verification of Calibration

Exemplary assay responses are shown in Appendix A. Calibrations for IL-6, TNF-α and CRP were verified by testing the recovery of the current National Institute for Biological Standards and Control (NIBSC) World Health Organization (WHO) Reference Standards. The current WHO standard for IL-6 is NIBSC code 89/548 (recombinant protein produced in CHO cells with post translational modifications), for TNF-α NIBSC code 88/786 (a natural human protein derived from human BALL-1 cells), and for CRP NIBSC code 85/506 from human plasma. Spike recovery of all three WHO standards were within acceptable limits across the assay ranges as shown in the figures and tables below. Note that for the TNF- α assay we found low recovery (about 30%) of the WHO standard in a reference kit (R&D Systems Quantikine HS catalogue # HSTA00D, data shown in Appendix B). Therefore comparisons of sensitivity and slopes of assay correlations of results of the Theranos System with those of R&D Systems kits will show different results due to their respective calibrations. For example, the R&D Systems Assay would report a TNF-α value of 4 pg/mL when the Theranos Assay reports 12 pg/mL. If desired by a customer the Theranos System can be configured (in calibration algorithms) to provide results matching those of R&D Systems assays (or those of other predicate assay). It is our intention however to continue to perform primary calibration of Theranos assays using International Standard materials whenever possible since predicate assays not so calibrated may be subject to lot-to-lot variation in calibration.

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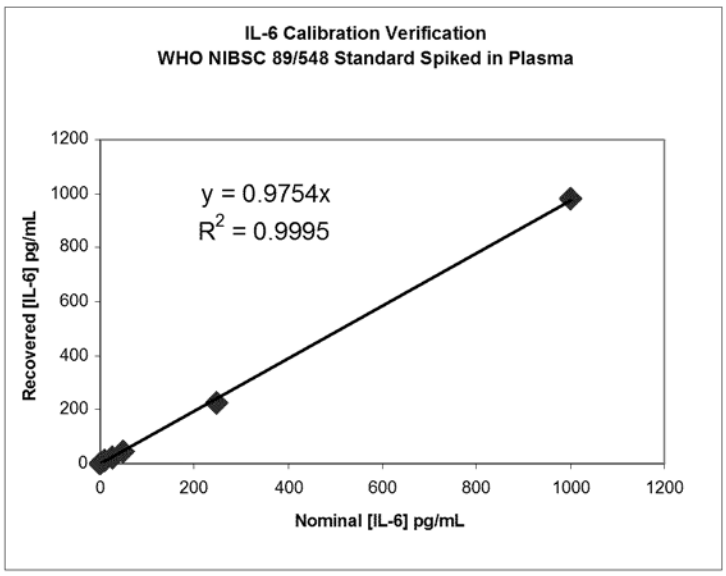

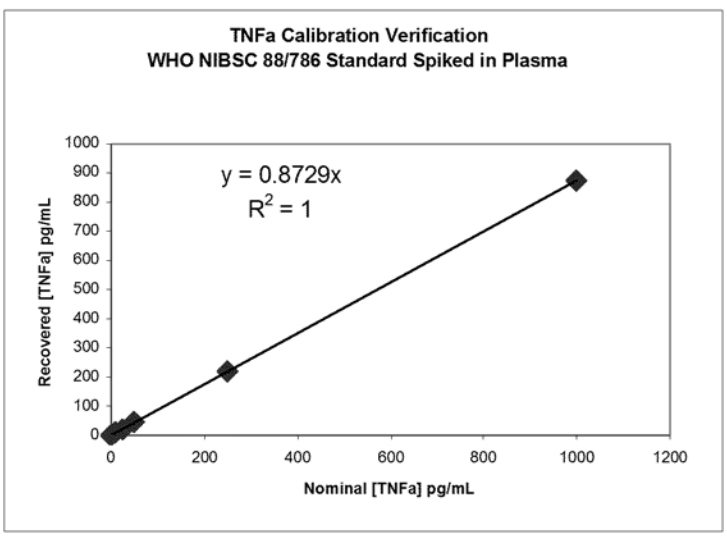

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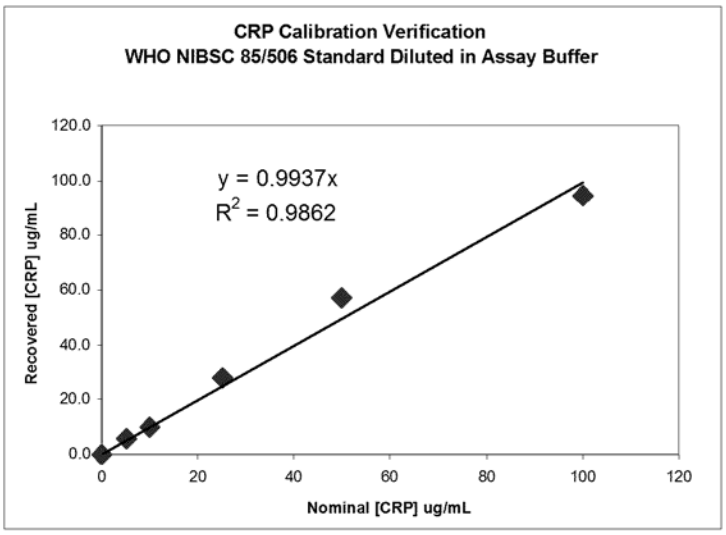

Theranos Systems Recovery of IL-6 (NIBSC code 89/548) Spiked in Plasma n=3 cartridges, 3 instruments per level					
[IL-6] IU/mL	[IL-6] pg/ml	Recovered [IL-6] pg/mL	CV %	Minus Endogenous	% Recovery
100	1000	981.1	11	980.1	98
25	250	227.1	16	226.2	90
5	50	45.2	10	44.2	88
3	25	21.5	8	20.5	82
1	10	10.5	9	9.5	95
0	0	1.0	47	0.0	N/A

Theranos Systems Recovery of TNF-α (NIBSC code 88/786) Spiked in Plasma n=3 cartridges, 3 instruments per level					
[TNFa] IU/mL	[TNFa] pg/mL	Recovered [TNF-α] pg/mL	CV %	Minus Endogenous	% Recovery
46.5	1000	873.4	3	873.0	89
11.6	250	218.7	3	218.3	96
2.3	50	44.0	10	43.5	96
1.2	25	20.9	22	20.4	95
0.5	10	10.9	19	10.5	100
0	0	0.4	14	0.0	N/A

Theranos Systems Recovery of CRP (NIBSC code 85/506) in Assay Buffer n=3 cartridges, 3 instruments per level				
[CRP] IU/mL	[CRP] ug/ml	Recovered [CRP] ug/mL	CV %	% Recovery
98	100	94.6	2	95
49	50	57.4	18	115
24.5	25	28.1	15	113
10	10	10.2	14	102

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4.9	5	5.7	20	114
0	0	0.0	30	N/A

4. Range

Reportable ranges based on calibration to WHO standards determined for these assays are:

Assay	Low	High
IL-6	2 pg/mL	1000 pg/mL
TNF-α	4[1] pg/mL	1000 pg/mL
CRP	0.05 ug/mL 100	ug/mL

As shown below, all three tested lots support these ranges[2].

5. Quantitation Limits

Assay calibrations and determination of Lower Limit of Quantitation (LLOQ) and Upper Limit of Quantitation (ULOQ) were performed and analyzed by proprietary software. Assay responses were fitted by a four-parameter equation and LLOQ and ULOQ determined according to FDA criteria. Calibrators were run in triplicate on three days (consecutive or non-consecutive) on 36 instruments for a total of nine cartridges per level, at 12 levels.

Summary of Calibration Analysis for three Cartridge Lots

Lot 2455142005	**IL-6**	**TNF-α**	**CRP**
LLOQ	1.3 pg/mL	6.3 pg/mL	0.05 ug/mL
ULOQ	1000 pg/mL	1000 pg/mL	150 ug/mL
Lot 2455146006	**IL-6**	**TNF-α**	**CRP**
LLOQ	1.3 pg/mL	6.3 pg/mL	0.05 ug/mL
ULOQ	1000 pg/mL	1000 pg/mL	150 ug/mL
Lot 2455156002	**IL-6**	**TNF-α**	**CRP**
LLOQ	2.3 pg/mL	6.3 pg/mL	0.05 ug/mL
ULOQ	1000 pg/mL	1000 pg/mL	150 ug/mL

Limits of detection (LOD)

The range in the Limits of detection calculated as 2*Signal SD/Slope of dose response (□signal/□conc) are reported for the three lots of Theranos cartridges. Comparison data are also given for R&D Systems assays Minimum Detectable Dose "MDD" (which is equivalent to LOD). In addition to the calibration issue for the R&D Systems TNF-α assay discussed above

[1] Equivalent to 1 pg/mL in the R&D Systems assay calibrated using R&D Systems calibrators

[2] The lower limit of the reportable range of the TNF-α assay has been extended below the LLOQ so as not to restrict the reportable range too much. The LLOQ is higher than anticipated due to unexpectedly high imprecision of the assay in the cartridge lots used for validation compared with other cartridge lots used in pre-clinical work. We are presently investigating the root cause of this imprecision.

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which gives a four-fold lower limit for R&D Systems, we believe the calculation of MDD performed by R&D Systems may be compromised (falsely low) by the inability of any known spectrometer to report optical density to the required precision needed to support the calculated values.

The CRP MDD reported by R&D Systems is highly misleading since it represents the concentration in the assay rather than in the sample (which "must be diluted" according to their package insert prior to assay). Note that the Theranos assay uses a sample which is diluted 5000-fold. If we compare the actual sensitivity *in the assay medium* the Theranos value would be about 0.006 ng/mL.

Assay System IL-6 (pg/mL) TNF-		α(pg/mL) CRP (ng/mL)	
Theranos	0.9 – 1.5	3.7 – 5.2	28 - 31
R&D Systems 0.02 – 0.11		0.04 – 0.19	0.005 – 0.22
R&D Systems[3]		0.16 – 0.76	

6. Precision and Accuracy

Plasma with low endogenous analyte levels was spiked with three levels of the analytes were measured in 16 cartridges per level on 48 instruments. Recovery of the spiked analyte was good. Imprecision (% CV) ranged from 10 - 25 %. Note that the imprecision cited includes both instrument-instrument and cartridge-cartridge variance.

Spiked Plasma Samples (n=16 cartridges, n=48 instruments)

Nominal [IL-6] pg/mL	Recovered [IL-6] pg/mL	StDev	CV %	% Recovery
800.3	806.9	79.8	9.9	101
50.3	50.5	4.7	9.2	100
5.3	5.1	0.8	15.5	96
Nominal [TNFa] pg/mL	**Recovered [TNFa] pg/mL**	**StDev**	**CV %**	**% Recovery**
500.3	418.9	39.6	9.5	84
50.3	42.7	5.1	12.0	85
12.3	12.9	3.2	24.6	105
Nominal [CRP] ug/mL	**Recovered [CRP] ug/mL**	**StDev**	**CV %**	**% Recovery**
50.1	50.4	10.0	19.9	101
1.6	1.6	0.3	16.8	97
0.1	0.1	0.0	20.6	103

7. Specificity

Assays were tested for cross reactivity and interference by the factors listed below, at high, mid and low analyte levels. Potential cross-reactants were selected based on package inserts of recognized predicate methods and added at levels deemed to be higher than those likely to be

[3] Recalculated to reflect calibration to WHO standard material

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found in clinical samples. No significant cross reactivity or interference was observed for any of the assays by any of the tested factors at all analyte levels tested.

IL-6 Assay Specificity Test in Spiked Plasma (n=3 cartridges, 3 instruments per level)					
Substance	[Test Substance] ng/mL	Target [IL-6] pg/mL	Recovered [IL-6] pg/mL	CV %	% Recovery
Control	0	1000.3	1100.3	7.8	110
	0	90.3	95.8	16.6	106
	0	8.3	9.4	4.8	113
IL-1α	10	1000.3	939.2	2.9	94
	10	90.3	97.0	15.7	107
	10	8.3	9.0	6.9	108
IL-2	10	1000.3	1047.7	1.7	105
	10	90.3	86.7	9.4	96
	10	8.3	8.7	22.3	105
IL-3	10	1000.3	950.0	12.7	95
	10	90.3	91.9	4.6	102
	10	8.3	7.9	4.4	95
IL-4	10	1000.3	908.0	10.9	91
	10	90.3	79.9	16.7	88
	10	8.3	8.1	18.1	97
IL-6 sR	50	1000.3	914.9	18.0	91
	50	90.3	81.2	1.3	90
	50	8.3	8.0	29.0	96
IL-7	10	1000.3	895.0	10.0	89
	10	90.3	78.1	9.1	87
	10	8.3	8.2	9.4	99
IL-8	10	1000.3	927.8	9.7	93
	10	90.3	82.3	17.1	91
	10	8.3	8.4	17.6	101
IL-11	10	1000.3	897.5	12.5	90
	10	90.3	90.3	6.1	100
	10	8.3	7.9	2.2	95
IL-12	10	1000.3	837.6	8.4	84
	10	90.3	85.8	14.7	95
	10	8.3	6.8	18.1	82
CNTF	10	1000.3	900.6	8.4	90
	10	90.3	95.3	5.8	106
	10	8.3	8.9	22.4	107
G-CSF	10	1000.3	925.0	18.7	92
	10	90.3	90.2	12.8	100
	10	8.3	9.7	6.9	117
sgp130	1000	1000.3	895.5	17.0	90
	1000	90.3	88.6	2.0	98

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IL-6 Assay Specificity Test in Spiked Plasma (n=3 cartridges, 3 instruments per level)					
Substance	[Test Substance] ng/mL	Target [IL-6] pg/mL	Recovered [IL-6] pg/mL	CV %	% Recovery
	1000	8.3	9.4	3.2	114
LIF R	50	1000.3	895.2	2.8	89
	50	90.3	78.5	16.5	87
	50	8.3	8.9	19.8	107
OSM	10	1000.3	945.4	9.5	95
	10	90.3	77.1	10.0	85
	10	8.3	6.9	16.8	83
TNF-β	10	1000.3	919.6	8.6	92
	10	90.3	83.3	15.8	92
	10	8.3	9.4	7.8	113
IL-1β	10	1000.3	901.2	8.1	90
	10	90.3	85.7	17.6	95
	10	8.3	7.5	10.5	90
sTNF RI	10	1000.3	1025.2	9.2	102
	10	90.3	83.4	11.4	92
	10	8.3	9.4	16.5	114
sTNF RII	10	1000.3	963.3	13.8	96
	10	90.3	90.7	10.2	100
	10	8.3	9.3	21.0	112

TNF-α Assay Specificity Test in Spiked Plasma (n=3 cartridges, 3 instruments per level)					
Substance	[Test Substance] ng/mL	Target [TNFa] pg/mL	Recovered [TNFa] pg/mL	CV %	% Recovery
Control	0	900.3	883.7	4.1	98
	0	90.3	85.4	4.1	95
	0	8.3	8.3	40.4	100
IL-1α	10	900.3	849.1	5.5	94
	10	90.3	89.6	12.7	99
	10	8.3	8.8	16.0	106
IL-2	10	900.3	855.2	23.5	95
	10	90.3	90.8	7.9	101
	10	8.3	9.6	18.5	116
IL-3	10	900.3	836.5	23.5	93
	10	90.3	74.3	5.4	82
	10	8.3	8.2	29.2	98
IL-4	10	900.3	884.6	6.9	98
	10	90.3	89.5	8.5	99
	10	8.3	7.0	49.3	84
IL-6 sR	50	900.3	874.0	23.5	97
	50	90.3	77.8	13.8	86
	50	8.3	8.6	34.8	103
IL-7	10	900.3	871.9	6.3	97
	10	90.3	82.8	37.1	92

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TNF-α Assay Specificity Test in Spiked Plasma (n=3 cartridges, 3 instruments per level)					
Substance	[Test Substance] ng/mL	Target [TNFa] pg/mL	Recovered [TNFa] pg/mL	CV %	% Recovery
	10	8.3	7.6	22.9	91
IL-8	10	900.3	774.4	1.8	86
	10	90.3	83.4	13.5	92
	10	8.3	7.9	12.6	95
IL-11	10	900.3	901.8	1.5	100
	10	90.3	90.7	19.6	100
	10	8.3	9.3	36.8	112
IL-12	10	900.3	770.9	7.3	86
	10	90.3	77.4	15.8	86
	10	8.3	7.9	56.7	96
CNTF	10	900.3	920.1	6.0	102
	10	90.3	82.5	9.7	91
	10	8.3	8.7	18.9	105
G-CSF	10	900.3	1052.6	3.7	117
	10	90.3	95.6	20.7	106
	10	8.3	9.1	9.6	110
sgp130	1000	900.3	891.3	16.8	99
	1000	90.3	93.8	9.1	104
	1000	8.3	10.1	25.1	122
LIF R	50	900.3	781.5	20.7	87
	50	90.3	87.3	15.2	97
	50	8.3	9.1	12.1	110
OSM	10	900.3	862.1	10.6	96
	10	90.3	85.2	23.8	94
	10	8.3	7.4	54.1	89
TNF-β	10	900.3	804.0	24.7	89
	10	90.3	90.7	16.4	100
	10	8.3	7.7	32.3	92
IL-1β	10	900.3	900.0	17.3	100
	10	90.3	83.1	16.6	92
	10	8.3	8.3	33.1	101
sTNF RI	10	900.3	833.0	21.8	93
	10	90.3	86.4	19.5	96
	10	8.3	6.7	21.6	80
sTNF RII	10	900.3	801.3	8.9	89
	10	90.3	93.6	3.0	104
	10	8.3	8.2	14.2	99

CRP Assay Specificity Test in Assay Buffer (n=3 cartridges, 3 instruments per level)					
Substance	[Test Substance] ng/mL	Target [CRP] ug/ml	Recovered [CRP] ug/ml	CV %	% Recovery

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Control	0	50	53.0	16	106
	0	10	8.1	34	81
	0	0.75	0.7	13	91
Pentraxin-2/SAP	30	50	49.2	19	98
	30	10	8.9	9	89
	30	0.75	0.8	4	102
Pentraxin-3/TSG-14	10	50	40.6	7	81
	10	10	8.2	14	82
	10	0.75	0.7	5	100

8. Linearity

A plasma sample with low endogenous analyte levels was spiked with known levels of IL-6, TNF-α, and CRP then diluted serially with the unspiked plasma. All assays showed an appropriate linear dilution response across the dilution range (500 – 2000-fold). Data are tabulated and graphed below.

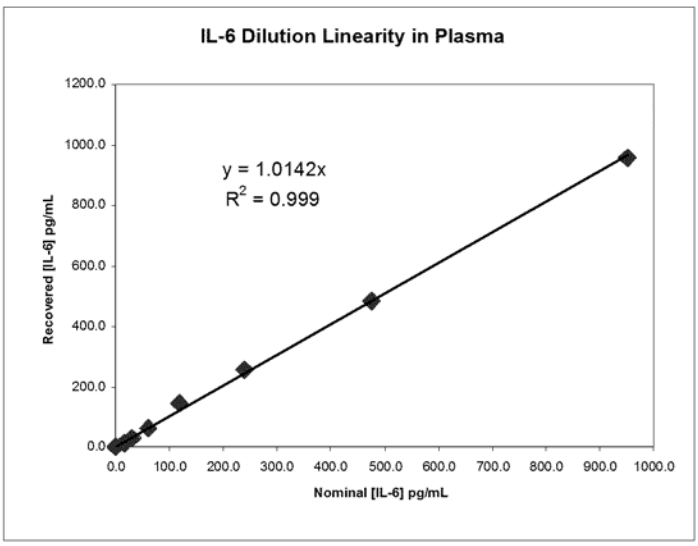
Dilution Linearity in Plasma, Multiplexed Assays (n=3 cartridges, 3 instruments per level)

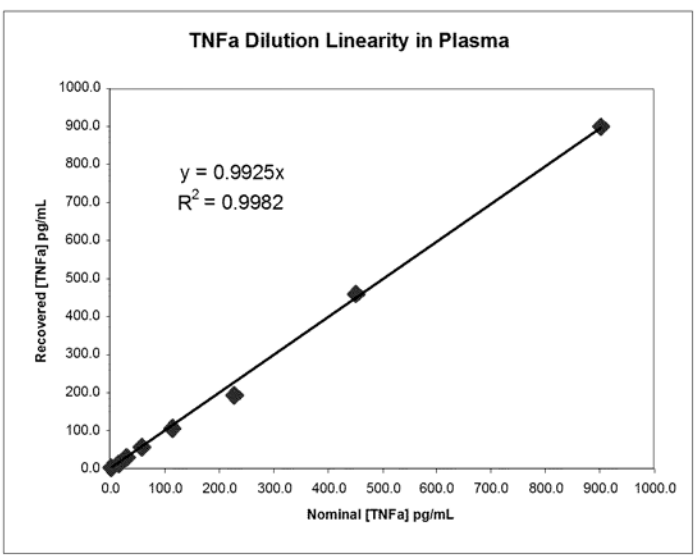
IL-6				
Spiked [IL-6] pg/mL	**[Expected] pg/ml**	**[Recovered] p g/mL**	**CV %**	**% Recovery**
950	950.5	958.1	7	101
	475.5	480.9	11	101
	238.0	256.1	18	108
	119.2	143.9	25	121
	59.8	62.3	3	104
	30.1	28.3	23	94
	15.3	13.3	34	87
	0.5	0.5	88	100

TNF-α				
Spiked [TNFa] pg/mL	**[Expected] pg/ml**	**[Recovered] p g/mL**	**CV %**	**% Recovery**
900	902.7	899.2	11	100
	452.7	461.5	9	102
	227.7	194.6	6	85
	115.2	105.0	11	91
	59.0	56.1	2	95
	30.9	30.6	4	99
	16.8	14.9	26	89
	2.7	2.7	14	100

CRP				
Spiked [CRP] ug/mL	**[Expected] ug/ml**	**[Recovered] ug /mL**	**CV %**	**% Recovery**
75	75.1	82.8	34	110
	37.6	35.0	0	93
	18.8	14.7	10	78
	9.5	9.1	12	96

	4.8	4.1	8	85
	2.4	2.4	7	98
	1.3	1.3	15	102
	0.1	0.1	29	100





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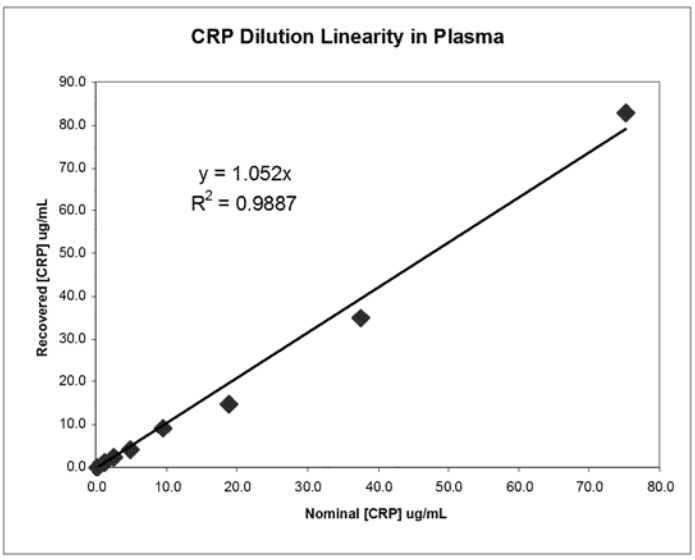

9. Matrix Effects

Plasma or serum containing various potentially interfering factors or substances were spiked with known levels of analyte and the resulting recovery of the spiked analyte calculated after correction for endogenous analyte. None of the assays showed interference from icteric, hemolyzed, lipemic, or rheumatoid factor-positive samples as shown in the tables below

NORMAL SERUM Sample: PromedDx 10739123 (n=3 cartridges, 3 instruments per level)

Spiked [IL-6] pg/mL	Recovered [IL-6] pg/mL	CV %	Minus Endogenous % Recovery	
1000	1019.1	14	1015.82	102
250	224.9	4	221.58	89
50	47.7	14	44.42	89
25	25.3	6	22.01	88
10	12.6	9	9.29	93
0	3.3	43	0.00	
Spiked [TNFa] pg/mL	**Recovered [TNFa] pg/mL**	**CV %**	**Minus Endogenous % Recovery**	
1000	1019.1	14	1014.7	101
250	224.9	4	220.5	88
50	47.7	14	43.3	87
25	25.3	6	20.9	84
10	12.6	9	8.2	82
0	4.4	60	0.0	
Spiked [CRP] ug/mL	**Recovered [CRP] ug/mL**	**CV %**	**Minus Endogenous % Recovery**	
100	107.4	11	107.3	107
50	49.3	13	49.3	99
25	25.0	23	24.9	100
10	9.6	41	9.5	95
5	5.9	17	5.8	116

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0	0.1	12	0.0	

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LIPEMIC SERUM Sample: Vital Products SFB8315 (n=3 cartridges, 3 instruments per level)

Spiked [IL-6] pg/mL	Recovered [IL-6] pg/mL	CV %	Minus Endogenous % Recovery	
1000	872.5	15	868.8	87
250	214.1	4	210.4	84
50	47.8	15	44.1	88
25	24.5	6	20.8	83
10	14.4	19	10.7	107
0	3.7	12	0.0	
Spiked [TNFa] pg/mL	**Recovered [TNFa] pg/mL**	**CV %**	**Minus Endogenous % Recovery**	
1000	965.0	17	962.8	96
250	230.8	15	228.6	91
50	56.6	40	54.4	109
25	25.4	13	23.2	93
10	14.8	14	12.6	126
0	2.2	32	0.0	
Spiked [CRP] ug/mL	**Recovered [CRP] ug/mL**	**CV %**	**Minus Endogenous % Recovery**	
100	119.4	36	119.1	119
50	54.2	40	53.9	108
25	24.4	25	24.1	96
10	10.4	9	10.1	101
5	5.8	15	5.6	111
0	0.2	12	0.0	

HEMOLYZED PLASMA Sample: Stanford W070509118560 (n=3 cartridges, 3 instruments per level)

Spiked [IL-6] pg/mL	Recovered [IL-6] pg/mL	CV %	Minus Endogenous % Recovery	
1000	1010.9	10	1010.0	101
250	274.6	13	273.7	109
50	51.6	2	50.7	101
25	26.8	11	25.9	104
10	10.5	12	9.6	96
0	0.9	41	0.0	
Spiked [TNFa] pg/mL	**Recovered [TNFa] pg/mL**	**CV %**	**Minus Endogenous % Recovery**	
1000	898.7	14	895.1	90
250	223.5	12	219.9	88
50	44.2	11	40.6	81
25	27.7	23	24.1	96
10	12.0	23	8.4	84
0	3.6	14	0.0	
Spiked [CRP] ug/mL	**Recovered [CRP] ug/mL**	**CV %**	**Minus Endogenous % Recovery**	
100	119.6	10	119.5	119
50	54.0	10	53.9	108
25	22.5	14	22.4	90
10	11.6	3	11.5	115
5	5.6	11	5.5	110
0	0.1	4	0.0	

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ICTERIC SERUM Sample: PromedDx 10739123 (n=3 cartridges, 3 instruments per level)

Spiked [IL-6] pg/mL	Recovered [IL-6] pg/mL	CV %	Minus Endogenous % Recovery	
1000	986.0	9	983.4	98
250	282.4	12	279.7	112
50	55.8	10	53.2	106
25	28.1	7	25.4	102
10	11.8	16	9.2	92
0	2.6	53	0.0	
Spiked [TNFa] pg/mL	**Recovered [TNFa] pg/mL**	**CV %**	**Minus Endogenous % Recovery**	
1000	969.8	5	967.4	97
250	219.6	22	217.2	87
50	45.0	11	42.6	85
25	24.5	5	22.1	88
10	10.6	22	8.2	82
0	2.4	17	0.0	
Spiked [CRP] ug/mL	**Recovered [CRP] ug/mL**	**CV %**	**Minus Endogenous % Recovery**	
100	109.5	8	108.4	108
50	41.7	80	40.6	81
25	29.6	14	28.4	114
10	10.1	11	9.0	90
5	6.4	19	5.3	106
0	1.1	3	0.0	

RHEUMATOID FACTOR POSITIVE SERUM Sample: Vital Products SFB7884 (n=3 cartridges, 3 instruments per level)

Spiked [IL-6] pg/mL	Recovered [IL-6] pg/mL	CV %	Minus Endogenous % Recovery	
1000	1118.0	10	1097.9	110
250	286.9	9	266.7	107
50	77.7	13	57.6	115
25	46.3	12	26.2	105
10	30.4	6	10.2	102
0	20.1	6	0.0	
Spiked [TNFa] pg/mL	**Recovered [TNFa] pg/mL**	**CV %**	**Minus Endogenous % Recovery**	
1000	1116.4	11	1112.3	111
250	228.9	5	224.8	90
50	48.0	13	43.9	88
25	24.2	13	20.1	80
10	14.0	20	9.9	99
0	4.1	27	0.0	
Spiked [CRP] ug/mL	**Recovered [CRP] ug/mL**	**CV %**	**Minus Endogenous % Recovery**	
100	110.9	18	105.8	106
50	49.1	17	44.0	88
25	34.2	29	29.0	116
10	15.5	9	10.3	103
5	10.9	11	5.7	114

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0	5.2	28	0.0	

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10. Stability

The stability of component reagents for the present assays has been studied individually in lots made previous to the present study. The capture surfaces were stable for over 12 months, and the detection conjugates for at least six months. Stability of the integrated cartridges used for this validation report stored at 4C is being monitored and an updated report will include this data. Cartridges are initially assigned an expiry date of three months post manufacture.

Conclusions:

The Theranos IL-6, TNF-α, CRP assay multiplex has been shown to give more accurate and precise results for three independently calibrated cartridge lots and all the many instruments used than current "gold standard" reference methods. Assay calibration has been established using WHO or other standard materials. Lower and upper levels of quantitation have been established. The assays are specific for their respective analytes when tested against potential cross reactants and are not interfered with by agents that may cause problems in immunoassays. Dilution linearity is satisfactory for all the assays. Assay cartridge stability studies are underway.

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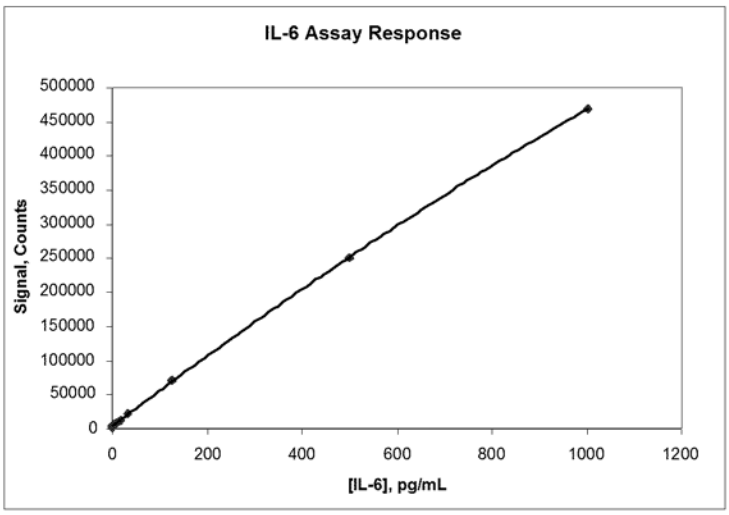
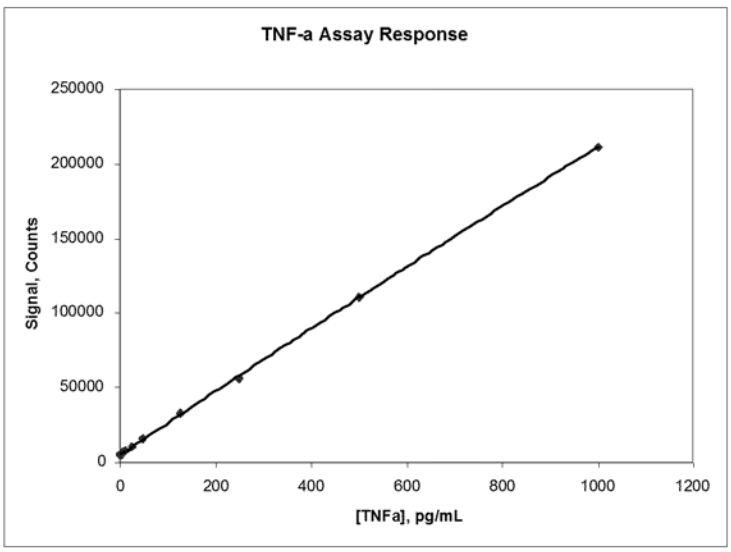
Appendix A





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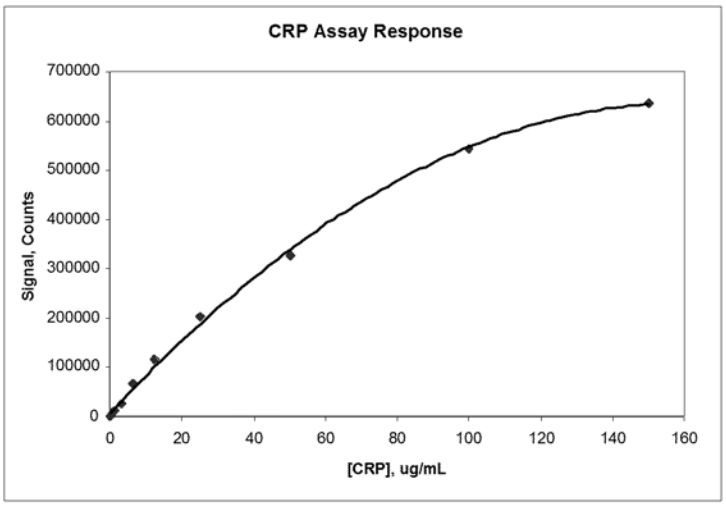

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Appendix B

Comparison of Theranos Systems TNFa Calibration to Other Available Commercial Methods

Plasma samples were spiked with WHO TNF-a Standard (NIBSC code 88/786) and run in Theranos Systems and in R&D Quantikine High Sensitivity Human TNF-α ELISA (catalogue # HSTA00D). The results are shown below.

THERANOS SYSTEMS Recovery of TNFa WHO Standard Spiked in Plasma

Nominal Spike		1pg/mL = 0.0465 IU/mL			
[TNFa] IU/ml	[TNFa] pg/ml	Calc. pg/mL	Minus Endogenous	Calc. IU/mL	% Recovery
0	0	5.2	0.0		
0.1	2.5	8.1	2.9	0.1	118
0.2	5	11.5	6.3	0.3	126
0.5	10	14.9	9.7	0.5	97
1.2	25	35.9	30.8	1.4	123
2.3	50	57.6	52.4	2.4	105
11.6	250	217.6	212.5	9.9	85
46.5	1000	1120.6	1115.4	51.9	112

R&D QUANTIKINE HS ELISA Recovery of TNFa WHO Standard Spiked in Plasma

Nominal Spike		1pg/mL = 0.0465 IU/mL			
[TNFa] IU/ml	[TNFa] pg/ml	Calc. pg/mL	Minus Endogenous	Calc. IU/mL	% Recovery
0	0	0.2	0.0		
0.1	2.5	1.0	0.8	0.04	32
0.2	5	1.8	1.6	0.07	32
0.5	10	3.2	3.0	0.14	30
1.2	25	7.3	7.1	0.3	28
2.3	50	15.0	14.8	0.7	30
11.6	250	83.6	83.4	3.9	33
46.5	1000	308.0	307.7	14.3	31

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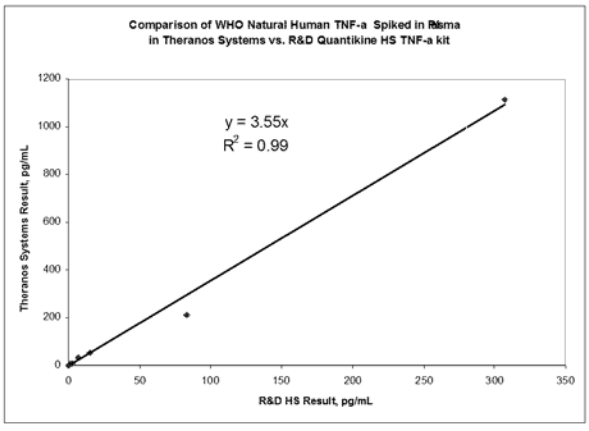

Exhibit 3

Message

From: Elizabeth Holmes [/O=THERANOS ORGANIZATION/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=EHOLMES]
Sent: 10/11/2008 1:08:44 AM
To: Power, Aidan C [aidan.c.power@pfizer.com]; Lipset, Craig [Craig.Lipset@pfizer.com]
CC: Marc Thibonnier [mthibonnier@theranos.com]
Subject: RE: Follow up to our meeting

Dear Aidan and Craig:

It is with great pleasure that I write to inform you we have now achieved our study goals.

In the interest of finishing as quickly as possible, we varied the enrollment schedules of some of our existing and new patients, as you will see in the attached.

Throughout this process, we have been compiling the data for our final report. I am very pleased to present you with the final data -- see the attached study report. We also have compiled all the raw data and included it for your reference in the attached spreadsheet. The report has been written in such a way that it could be circulated to people unfamiliar with Theranos.

Our 15 month study has validated the efficacy of our technology. We now have the foundation to apply it to
1) fast-tracking the approvals and label expansions of key therapies through generation of predictive and higher integrity data, faster and
2) significantly cutting costs to Pfizer's current study budgets by eliminating the need for sample shipments, overhead and analytical costs in the process.

The ability to profile protein time-courses in this way is allowing for predictive correlations to be extracted from biomarker measurements. One of our pharma partners quantified the impact of Theranos Systems accelerating time-to-market at $1M a day after seeing correlations in a 6 month study that the conventional infrastructure took over 2 years to uncover. This work is on label expansion of an existing drug into a new indication; the ability to rapidly generate data on efficacy dynamics for market expansion has further implications for the revenue of the drug.

Since our meeting, we have cemented thoughts on the most powerful application of these systems for Pfizer. I wanted to wait until we received some highly anticipated return-on-investment data to share with you and we will now compile an overview of our systems and potential program(s) for you.

We have worked very hard on the angiogenesis program for a long time and are looking forward to translating our work into significant value creation for Pfizer.

Let us know if there is a convenient time next week for us to connect on this and next steps.

With my very best regards,
Elizabeth.

Elizabeth Holmes
President and CEO
Theranos, Inc.

==========

From: Power, Aidan C [mailto:aidan.c.power@pfizer.com]
Sent: Friday, August 22, 2008 10:00 AM
To: Elizabeth Holmes; Lipset, Craig
Cc: Marc Thibonnier; Stefan Hristu
Subject: RE: Follow up to our meeting

Elizabeth – thank you for this. And thank you for hosting us on Tuesday. Aidan

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Theranos Angiogenesis Study Report

Prepared for Dr. Aidan Power
Pfizer, Inc.

Document Outline:

- Introduction to Theranos
- Background on Theranos Studies
- Economic Impact of Theranos Systems to Pharma
- Angiogenesis Program Overview
  - Study design
- Theranos System Overview
  - Specifications
  - Theranos System Performance
- Theranos Field Study
  - Field Performance Overview
  - Trial Data
  - Evaluation of time course results from individual patients
  - Review of generated data, in aggregate by patient ID, sex, cancer type, treatment, etc.
  - Integrated patient information, including date and time of monitoring, medication received, self evaluation of overall health status of each patient and other clinical data in a comprehensive format
  - Assessment of the technical performance of the Theranos System
    - Data transmission % success and mode of transmission used
    - General performance information as logged via the Customer Care line
    - Assessment of patient compliance with protocol
  - Summary of patient and clinical staff assessment of the Theranos System and the Client Solutions team via end-of-study surveys
- Conclusions
  - General
  - Technical
  - Economic

Introduction to Theranos:

Accurately, rapidly, and effectively profiling the efficacy dynamics of a therapy in clinical studies is an unmet need that has long challenged the conventional blood testing infrastructure.

Theranos has demonstrated in clinical studies that more frequent longitudinal time-series measurements on fresh whole blood samples with a multiplexed platform that eliminates the noise (and inability to accurately characterize very broad dynamic ranges) of conventional tests is imperative to effectively characterizing physiological changes and the efficacy of any intervention.

Theranos' wirelessly integrated data analytical system allows for 'baseline' profiles of pathway dynamics to be created and updated automatically as data is generated in the field. If needed, analyte selection or frequency of sampling can be adjusted at any time during the study based on the data coming in.

In future studies within a given indication, the data analytical infrastructure can be used for predictive modeling wherein new patient data can be indexed against the stored baseline profiles for earlier reads on efficacy dynamics and dose-response.

Background on Theranos Studies:

Every day gained in getting a new brand to market can be measured in millions of dollars.

Time is a major factor of cost of development of a new drug. For years the pharmaceutical industry has worked to drive every day possible out of the development process, and has reached a point where the physical limitations around the timelines for statistically significant data acquisition primarily determine the time to market.

Theranos Systems revolutionize those timeline constraints by enabling instant access to higher quality data and exponentially faster reads on efficacy and safety dynamics from the initiation of clinical trials. In doing so, Theranos is laying the foundation of a new growth model for pharma.

Theranos Systems radically impact revenues and growth on new and existing drugs in ways that were previously not possible:

- Faster approvals and studies - Immediate access to results enables immediate decision making and planning; early reads on efficacy dynamics and dose optimization for sub-populations through more comprehensive longitudinal PK/PD profiling
- Reimbursement and differentiation - Concrete reads on efficacy dynamics and visibility into mechanisms of action to optimize compounds dynamically
- Rapid access to multiple markets pre and post-approval - early reads on efficacy through trends in the change in rate of key markers allow for rapid label expansion
- Amelioration of safety concerns – more accurate reads on actual pathway dynamics enable rapid optimization where beneficial and delineation of patient sub-populations

Economic Impact of Theranos Studies to Pharma:

Based on Theranos' previous experience, predictive modeling and more comprehensive longitudinal profiling has resulted in the demonstration of meaningful dose-response and efficacy dynamics profiles in 6 month timeframes where the conventional infrastructure took two years and was still not able to generate hard correlations. An 18 month time-savings, not to mention the ability to gain insight into methods for optimization for label expansion, can conservatively be equated to hundreds of millions of dollars gained. With industry estimates at $1-3M a day for the value of each day gained in time to market, even 6 months saved ranges between $180M and $540M in return on investment.

Equally, once the infrastructure has been implemented, future studies are requiring about 25% fewer patients, reducing the patient costs, number of sites required, assay development, reagent screening, and infrastructure costs for shipping and processing samples through ambulatory point-of-care monitoring.

Overall savings on 6 month trials once the data analytical infrastructure has been established have averaged 50% of the cost of running an equivalent trial through the conventional infrastructure, further saving millions of dollars. As the data analytical engine evolves after the first 6 month study, costs are further reduced in each follow-on study, covering the cost of Theranos infrastructure and units many times over.

Ultimately though, the greatest economic return on investment lies in the ability to expand percentage market ownership through visibility into pathway dynamics that enables rapid characterization of responder populations in ways previously not possible. This capability enables commercialization of 'targeted blockbusters' by redefining a company's historical success rate in realizing the target product profile of each drug once it hits the market.

Angiogenesis Program Overview:

The primary objective of the present program was to demonstrate the functionality of Theranos Systems in such a way that future studies could fully leverage the power of comprehensive longitudinal time-series profiling for rapid compound optimization and development.

For this program, Theranos was asked to develop multiplexed point-of-care assays for VEGF and PlGF for use in monitoring patient pharmacodynamic response to anti-angiogenesis therapies. Because the development of VEGFR2 in that multiplex was desirable as a tool for use in future studies, Theranos developed the assay and included it in the point-of-care multiplex.

In this program, Theranos validated not only functional equivalence, but superior performance specifications of the Theranos multiplex to each of the respective 'gold-standard' kits.

An Interim Report on Assay Development was submitted to Pfizer in Q2 '07 upon successful completion of assay development.

As planned for at the interim update meeting with Pfizer, the first patient began participating in the study in July of 2007. In order to fast-track the program timeline, Theranos contracted an independent site - Tennessee Oncology Center.

Enrollment of Sutent patients at this site was very slow; from the time patient screening began (early 2007) and after discussions with respective members of the Pfizer team, the protocol was revised several times to increase the frequency of monitoring but reduce the total number of patients and shorten the monitoring cycles per patient. Likewise, enrollment criteria were broadened to include patients on other therapies with whom trends in the relevant markers could also be profiled.

In doing so, statistical significance in meeting the study goals could still be ensured. Multiple IRB submissions were filed. Final IRB and Informed Consent Forms were included in two interim update reports sent to Pfizer.

Goals of Study:

1. Generate preliminary data on VEGF and PLGF trends in cancer patients while assessing the use of the Theranos System in the hands of clinicians and patients.
2. Obtain feedback and recommendations from clinical staff.
3. Assess the use of the Theranos System in the hands of ambulatory patients at home.
4. Assess the Ambulatory Bioinformatics Communications System[1] including the physician and patient web portals as well as the data reports generated.

Study design:
Patient screening began in January 2007, once the final site was selected, enrollment began. In July of 2007, the first patient was enrolled in the trial. This trial consisted of very ill late-stage (4th line) cancer patients with various tumor types receiving a variety of therapies at the Sarah Cannon Research Center at Tennessee Oncology (TNONC) in Nashville, Tennessee. The patients in the study typically resided in very remote locations across the eastern US. Almost all patients were not computer literate, and most were from low income families, unable to afford private telephone service.

The Theranos angiogenesis monitoring system was evaluated for clinical efficacy and as a means of more accurately and effectively monitoring cancer therapy and the progression of solid

[1] The Ambulatory Bioinformatics Communication System (formerly known as ABCS) was rebranded as TheranOS, the Theranos Operating System.

tumor cancers from a mechanism-of-action perspective. 32 patients were enrolled. Various cycles of therapies were monitored as well as physical changes in tumor size.

Four of the patients retracted consent to the study, three of them due to family problems and one due to mental and physical instability. Thus, Theranos increased the targeted enrollment number to ensure that the goal of demonstrating performance across significantly significant patient numbers would be met. That goal has now been achieved. To realize the goal, some patients had extended (60 day) monitoring periods.

Since Theranos has the ability to continue monitoring patients under the existing IRB and given the power of some of the correlations which are becoming apparent, Theranos may continue monitoring those patients for an extended period of time.

Enrollment was unpredictable and slow. All installations and shipments completed for this study were done on-demand with less than 24 hours. As part of the installation procedure, Theranos' client solutions team has performed at-home installations and pick-ups for many weak patients.

For each patient, a total of up to 14 time points were collected during the month-long analysis period, 3-4 time points taken at the clinic and the other 10-11 time points taken in-home. Both finger-stick and venous samples were taken during each clinic visit, while only finger-stick samples were run in-home. The venous draw samples were run on the Theranos System in the clinic at the time of the draw; these samples were also processed so that the plasma and/or serum was analyzed using a reference method.

Venous samples were processed using reference methods and provide an archive of 41 anti-coagulated plasma and serum samples which were frozen and have subsequently been analyzed at Theranos.

Theranos System Overview:

The Theranos System is comprised of consumer-oriented readers, single-use cartridges containing assay chemistry and controls, and a data collection system that communicates through cellular networks with the instrument to provide assay protocols and to compute and display results.

The steps required of a new patient are to 1) take the machine out of the box and 2) plug it into a power source. The touch-screen then walks each patient through the process of poking his/her finger, depositing blood into the cartridge, and placing the cartridge in the reader drawer. The instrument then processes the assays and sends the data through the cellular network in real-time to a secure web-portal.

Theranos Systems allow for quantitative, multiplexed longitudinal time-series measurements to map correlations between the rate of change of blood-borne markers over time to surrogate and clinical end-points.

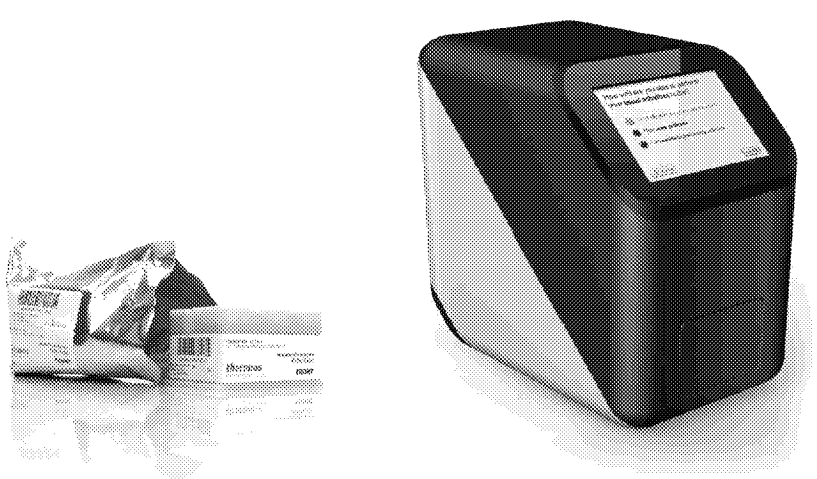
<u>Specifications:</u>

- Designed for at home use. Can also be used in physician's offices, ICU, and laboratories.
- Multiplexed measurement of biomarkers.
- Customizable for different/new assays on demand.
- Average 6 measurements per cartridge
- Serial measurements to comprehensively profile pharmacodynamic response through trends
- Runs fresh whole blood, plasma or serum samples

- Finger-stick – small sample size
- Mix and match selection of analytes on demand.
- Wide measurement range
  - pg/mLl – mg/mL (1 billion fold)
- High sensitivity
  - 0.2 pg/mL (2 parts per 10-billion)
- Analyte Recovery: ~100 %
- System CV post-calibration (inter-intra reader, cartridge, and assay): < 10 %
- On-board chemistry controls
- Factory calibration (no user calibration)
- Wireless communication of results to appropriate user through cellular network
- Proprietary algorithms to interpret time trend results

The existence of a technology infrastructure for home, real-time blood monitoring allows collection of information which cannot be obtained using conventional blood testing scenarios:

- Small sample (finger-stick) + more frequent sampling of a small subset of analytes enables:
  - Identification of appropriate analytes (greatly helped by more frequent sampling)
  - Earlier detection of efficacy and safety and acute problems so intervention (for example, dose modification or change in drug type) can be more effective
  - Convenience of monitoring through-out a time-course before an event
- Higher sample integrity; real-time sample analysis on fresh whole blood on a standardized platform which can be deployed at any location (world-wide) eliminates assay inaccuracy associated with commercially available tests performed on samples which are “old” by the time they are analyzed.
  - Elimination of erroneous results (caused by analyte instability) and inherent errors in data and patient correlations (caused by processing data at various contract locations)



For this study, an instrument was deployed in the home of each patient; four others were installed at the Cancer Center.

Three assays were performed simultaneously in multiplex by the system on a finger-stick sample of fresh whole blood. The analytes were Vascular Endothelial Growth Factor (VEGF), soluble VEGF receptor R2 (sVEGFR2, usually referred to as VEGFR2) and Placental Growth Factor (PLGF). Each assay was controlled using within-cartridge control measurements.

The system was calibrated at Theranos. Multiple cartridge lots were produced each with successively more clinically relevant specifications once samples were received from patients in the trial, as samples were not available during assay validation. Each lot was independently calibrated.

Traceability of calibration: Calibration is traced to authentic analytes dissolved at known concentrations in a plasma-like matrix. Calibration materials are prepared as mixed solutions of the three analytes. Assignment of calibrator concentrations is then made to values found for measurements of calibrators using reference assays.

System Performance Goals:

Assay	Reportable low pg/mL	Reportable high pg/mL	Precision CV, %
VEGF	20	10,000	10
VEGFR2	150	15,000	10
PLGF	5	1,000	10

Assay ranges achieved:
The goals for each assay's dynamic range were achieved. Due to the inability to receive samples for calibration at the beginning of the studies, the upper limit of calibration for VEGF was restricted to 3,000 pg/mL in the first cartridge lots, but then extended[2] to 10,000 pg/mL. For early cartridge lots the PLGF assay lower limit of sensitivity was 50 pg/mL. Therefore, many early results for PLGF were out-of-range low ("OORL"). Lots produced after receiving samples for calibration have reportable ranges below 20 pg/mL.

Specificity:
The specificity of the assays depends on the pairs of antibodies chosen for each assay. In the first instance, we rely on the antibody vendor information. Selected pairs are known to have good specificity in ELISA assays. Key issues for these analytes are (1) the structural relationship of VEGF and (2) the fact that VEGF binds to sVEGFR2. We have shown that the Theranos assay system is not affected by the presence of VEGF and VEGFR2 and PLGF in the same samples. In many patients in this study, the drug Avastin is used. This drug is an antibody that binds to VEGF. It is obvious that ELISA assays for VEGF (and perhaps VEGFR2) using antibody pairs are likely to be interfered with by Avastin. As documented below, Theranos assays for VEGF and VEGFR2 appear to function with minimal interference from Avastin. In contrast, the selected reference assay for VEGF is strongly interfered by Avastin.

Theranos System Performance:

Assay accuracy:
Accuracy has been evaluated by analysis of clinical samples. Two sets of samples have been used: (1) A set of 12 serum samples from cancer patients (obtained from a commercial vendor), (2) 41 archived serum and plasma samples from this study. Because Avastin was used to treat many of the patients in the TNONC study and this antibody strongly interferes with the reference method, we used the commercially available samples for VEGF assay evaluation.

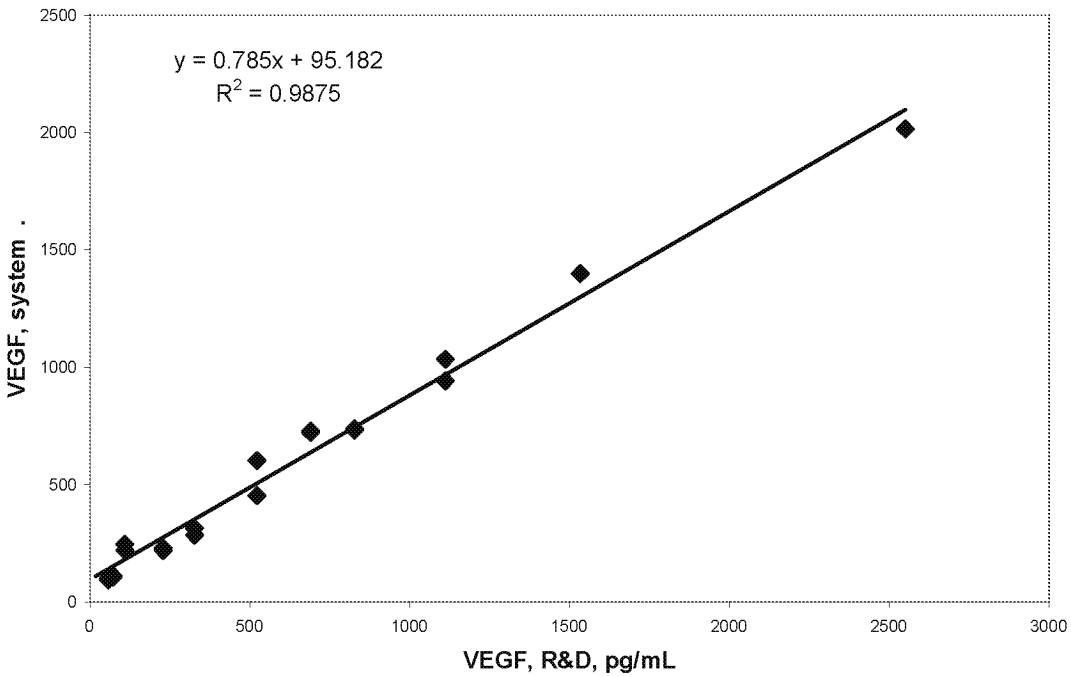
Twelve serum samples were assayed (singlicate) in the Theranos system and in duplicate for the reference method with the following results:

VEGF: y (Theranos) = 0.785 x (reference) + 95.2; R^2 =0.99. Range 96 – 1985 pg/mL. One sample was rejected from the analysis giving very high results in the Theranos system and low

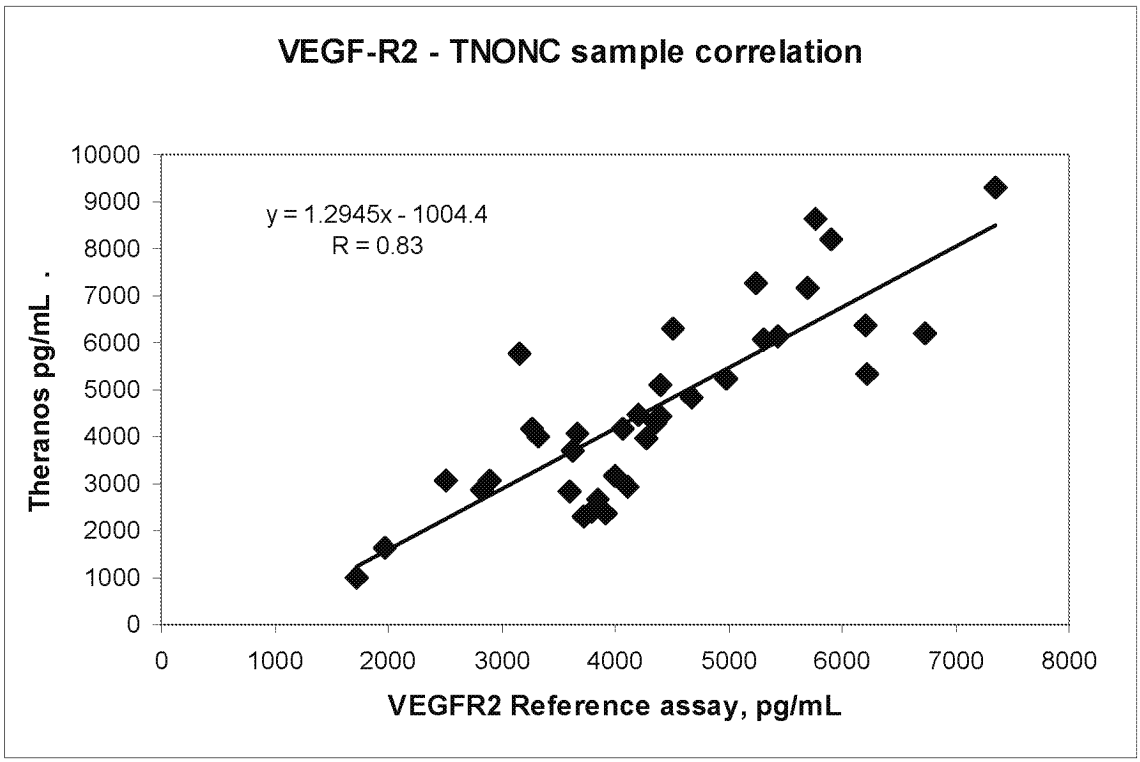
[2] All three assays have a linear dose-responses extending far above the highest calibrator used.

results in the reference assay. Based on the study data, it seems likely this patient was being treated with the drug Avastin, which interferes with the reference assay.

Single cartridge clinical results

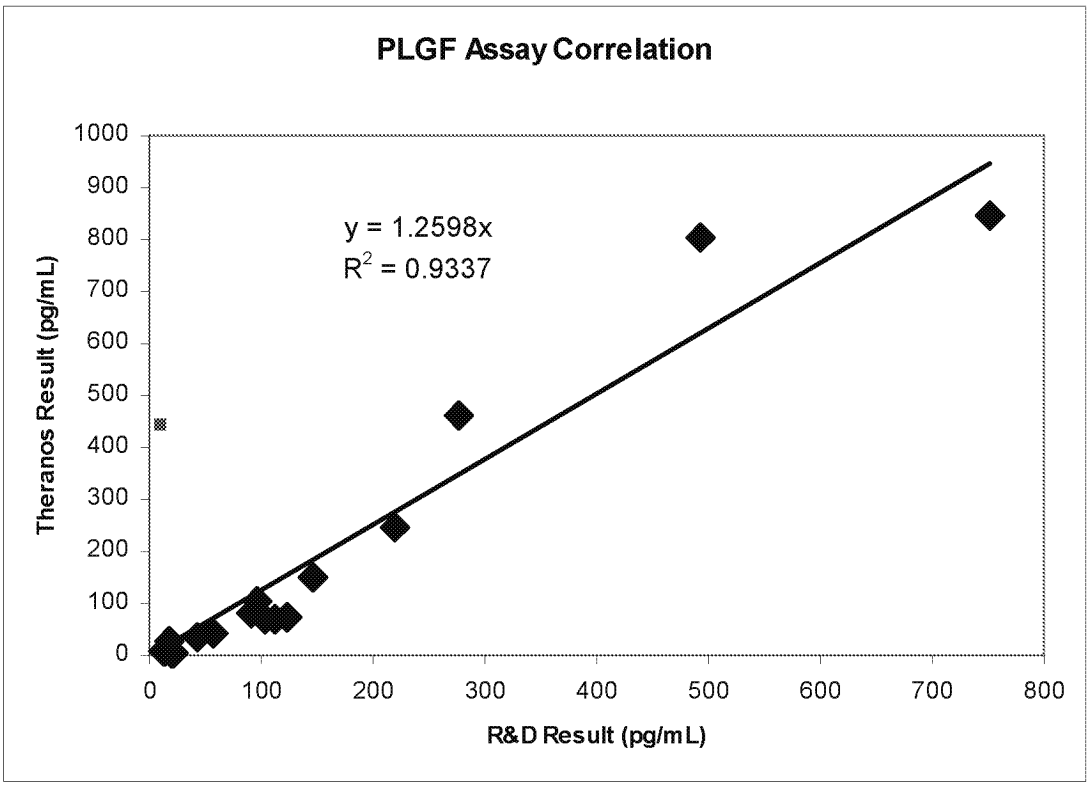


For VEGFR2, 39 TNONC samples were assayed in triplicate in the Theranos system and duplicate for the reference method. The results were: y (Theranos) = 1.29 x (reference) + 1004; R =0.83. Range 1015 – 9285 pg/mL.

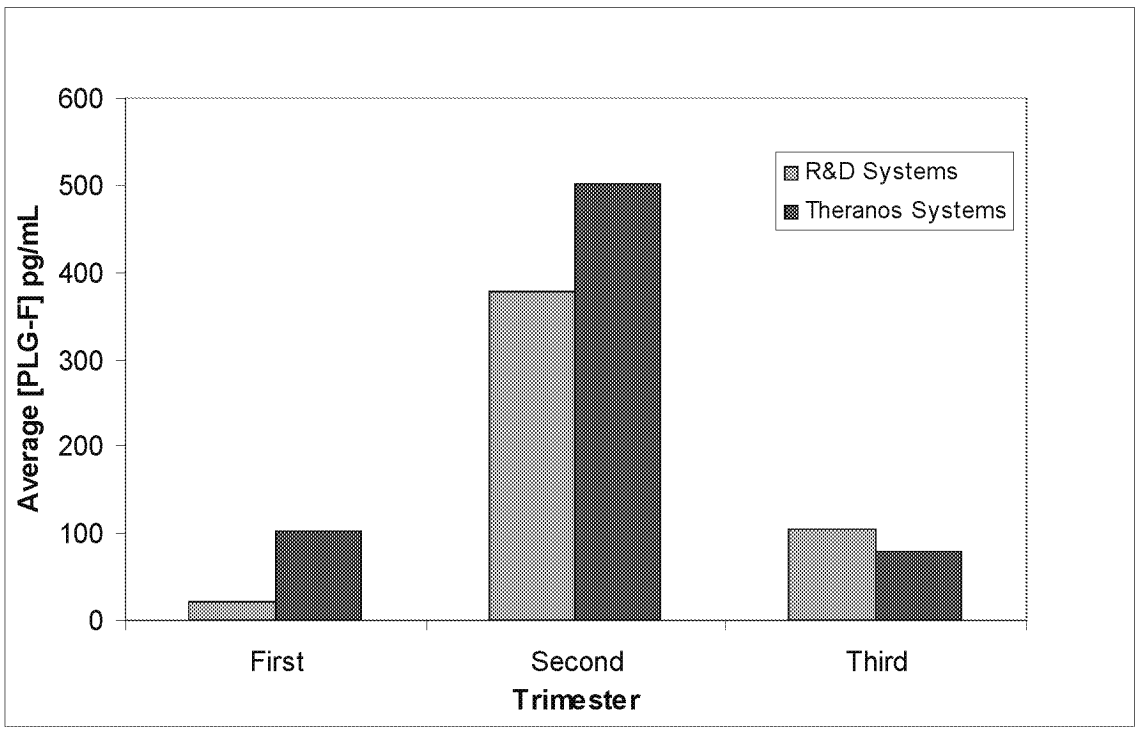


For the initial PLGF samples analyzed by Theranos in the field and with the reference method the results fell mostly in the undetectable range of both methods. Once the Theranos calibration was re-optimized, values became detectable from 5-17 pg/mL in the out-of-range-low venous samples sent to Theranos.

A significant correlation was achieved during validation on normal serum samples from twenty pregnant women assayed in quadruplicate. They were analyzed on both the Theranos system and the reference R&D Systems kit. The following results were obtained: y (Theranos) = 1.26*x (R&D Systems); R = 0.96. The average within sample CV for the Theranos results was 9%. One sample (shown in pink) below gave discrepant results.



When the results for patients were segregated by trimester and averaged, the concordance shown below was found.



Effect of Avastin on the reference VEGF assay:
Comparison of reference and Theranos VEGF assay results for venous samples were not correlated. Many Theranos results were in the thousands of pg/mL where reference assay gave a low value. Since it was noted that many of the patients had been treated with Avastin which binds to VEGF, Theranos did a study of spike recovery for the reference method. VEGF (400 pg/mL) was added to each sample and the assay repeated. Results are shown below:

Avastin Present	VEGF average, pg/mL Ref	VEGF average, pg/mL Theranos
N	149	588
Y	136	8359

	VEGF spike recovery, %
N	66.5
Y	-1.3

It is evident that Avastin completely blocks the reference assay response. Presumably, Avastin binds at a site on VEGF close to or identical with that recognized by one of the antibodies used in the reference method. The reference assay thus responds only to free VEGF whereas the Theranos assay is not blocked and measures both Avastin-bound and free VEGF.

Assay precision:

Inter-Instrument Precision:
Venous samples from patients were run across four instruments.

Assay	Reportable low pg/mL	Reportable high pg/mL	Precision CV, %
VEGF	20	10,000	8.0
VEGFR2	150	15,000	7.3
PLGF	5	1,000	9.2

Precision in comparison to available reference methods was evaluated during calibration. Singlicate measurements from six instruments were used next to commercially available 'gold-standards'. Theranos adjusted the target range after obtaining clinical samples. Due to the superior performance characteristics of Theranos' assay next to commercial standards, obvious variances are seen where the reference methods report OORL.

Single lot calibration data:

Analyte	Range (pg/mL)	Average CV, %
VEGF (lot 3)	30 – 10,000	12.0
VEGF (lot 1)	30 – 3,000	10.0
VEGFR2 (lot 3)	1,000 – 10,000	4.8
VEGFR2 (lot 1)	50 – 800	17.6
PLGF (lot 3)	5 – 780	26.9
PLGF (lot 1)	50 – 800	9.1

Precision was also measured by analysis of the 41 archived clinical samples in assays and for VEGF 12 commercial samples.

Analyte	Range (pg/mL)	Average CV, %
VEGF	30 – 10,000	16.7
VEGF[3]	96 – 1985	5.7
VEGFR2	1,000 – 10,000	20.4
PLGF	5 – 780	28.7

Dilution linearity:

Data gathered during lot calibration.

VEGF, pg/mL	Recovery, %
10000	(100)
2970	102
990	95
297	105
100	109
30	105
10	101

[3] Commercial samples

VEGFR2, pg/mL	Recovery, %
10560	(100)
7920	92.9
5280	100.9
3960	104.8
2640	97.7
1320	100.8

PLGF, pg/mL	Recovery, %
780	100.0
312	87.6
156	102.8
47	106.3
16	92.4
5	99.4

For all assays, recovery was close to 100 % in the reportable range.

Limit of detection (LOD):
Data gathered during calibration. The LOD is defined at a 95 % confidence level.

Analyte	LOD, pg/mL
VEGF	< 20
VEGFR2	< 200
PLGF[4]	< 20

Theranos Field Study:

The system has been deployed to patient's homes and the TNONC study clinic and has downloaded protocols and uploaded data wirelessly. Some patients used direct telephonic communications (POTs modems) if they were worried about cell reception. Data for every patient has been profiled on a secure, Pfizer-specific server.

Field Performance Overview:

In this report we document results from:

- 27 patients (41% female and 59% male)
- 13 cancer types
- 38 Instruments
  - 27 instruments deployed to patients' homes
  - 4 instruments deployed to the clinical site in Nashville, TN
  - 4 updated instruments to replace the readers at the clinical site such that the latest design revolution is deployed at the site

[4] Later stage cartridge lots

- 3 were used to replace malfunctioning readers in the field (2 at clinic - one with communication issue, one mechanical due to user error; 1 at patient's home with mechanical issues from shipping)
- 445 cartridges (approximately 1300 assay results)
  - This number includes cartridges run in-house on archived plasma as well as results gathered in-field

Data acquisition has proven feasible in the home setting. There were instruments in the field operating in extreme temperature conditions (from very hot, no A/C to A/C turned to the maximum) as well as in very diverse locations (from RV's to log cabins in the middle of forests), in remote, difficult to reach areas where poor cellular reception is prevalent.

The instruments have been deployed across three states, including Kentucky, Pennsylvania and Tennessee. As mentioned, typical turnaround time for installation and patient at-home test was less than 24 hours without notice.

In monitoring this multiplex of analytes at far greater frequency than ever before, considerable patient-response variation can be seen across different sub-patient populations, therapies, and cancer types.

When we look at the average results from each patient and the variation seen for each patient, it is evident that the patients vary drastically:

	VEGF Avg., pg/mL	VEGFR2 Avg., pg/mL	PLGF Avg., pg/mL
Maximum	13,584	6,317	410
Minimum	47.5	368	37.3

By evaluating sample statistics such as these, one can identify patients who are anomalous and who may benefit from therapy modification.

For example, of the 13 patients with colon cancer we see one subject with an average VEGF of 13,600 pg/mL and another with an average of 255 pg/mL whereas most of the patients had VEGF values quite closely clustered at 1000 - 5000 pg/mL. Similarly, we see some subjects who show very little variation in analyte values and others with wide variations presumably related to response (high or low) to therapy.

Trial Data:

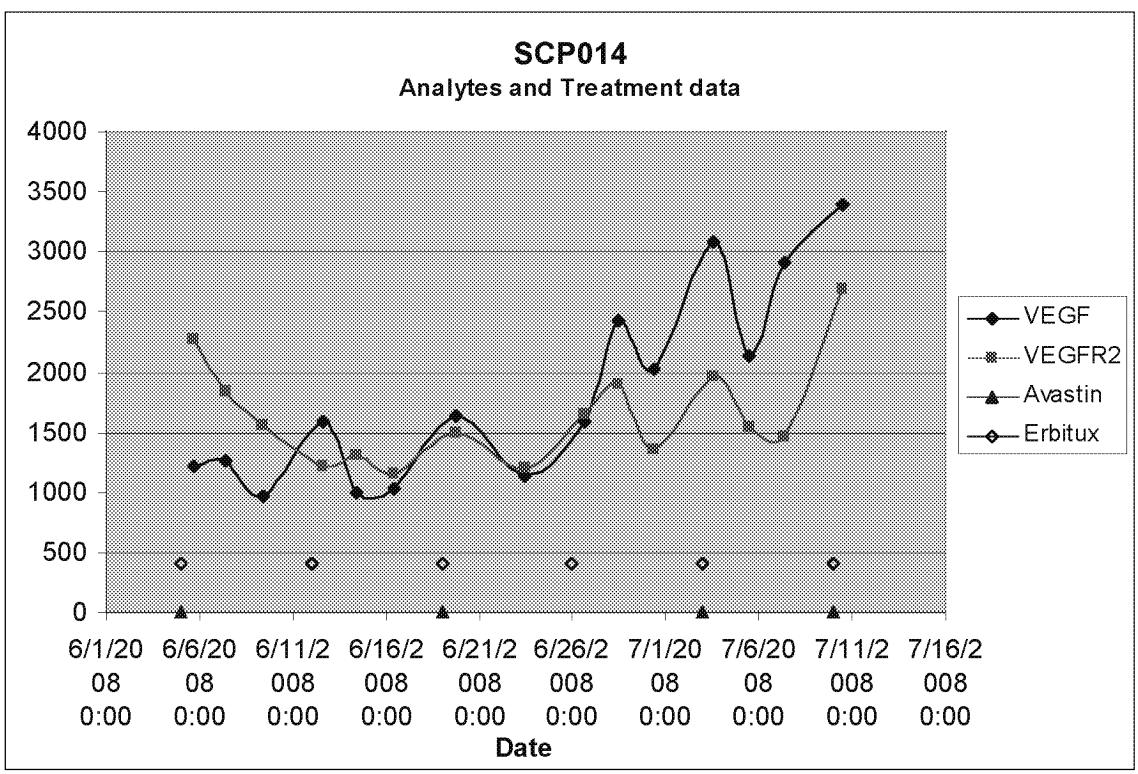
The following raw trial data is included in the appended spreadsheet:

1. Clinic visit diagnostics (Patient characteristics and Clinical assay results)
2. Clinic visit pivot table (clinical results presented as a customizable pivot table)
3. Patient aggregate data (Compliance data, Result averages and CVs by patient and averages by cancer type)
4. All field analyte data results (from the Theranos system presented by patient in a filtered table format [sort-able])
5. Treatment data (drugs used and dosage)
6. Individual end-of-study results (patient evaluation of system)
7. Compilation and summary of end-of-study survey results
8. Data transmission statistics

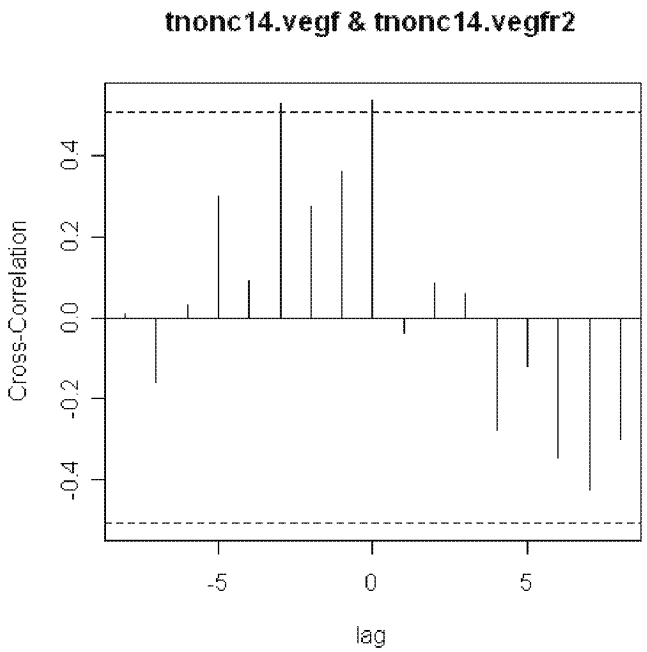
Evaluation of time course results from individual patients:

The study data demonstrates that in a larger, statistically controlled study, where the endpoint is directly proportional with patient outcome, e.g., a RECIST Score, a correlation between analyte dynamics and patient response to treatment would be generated.

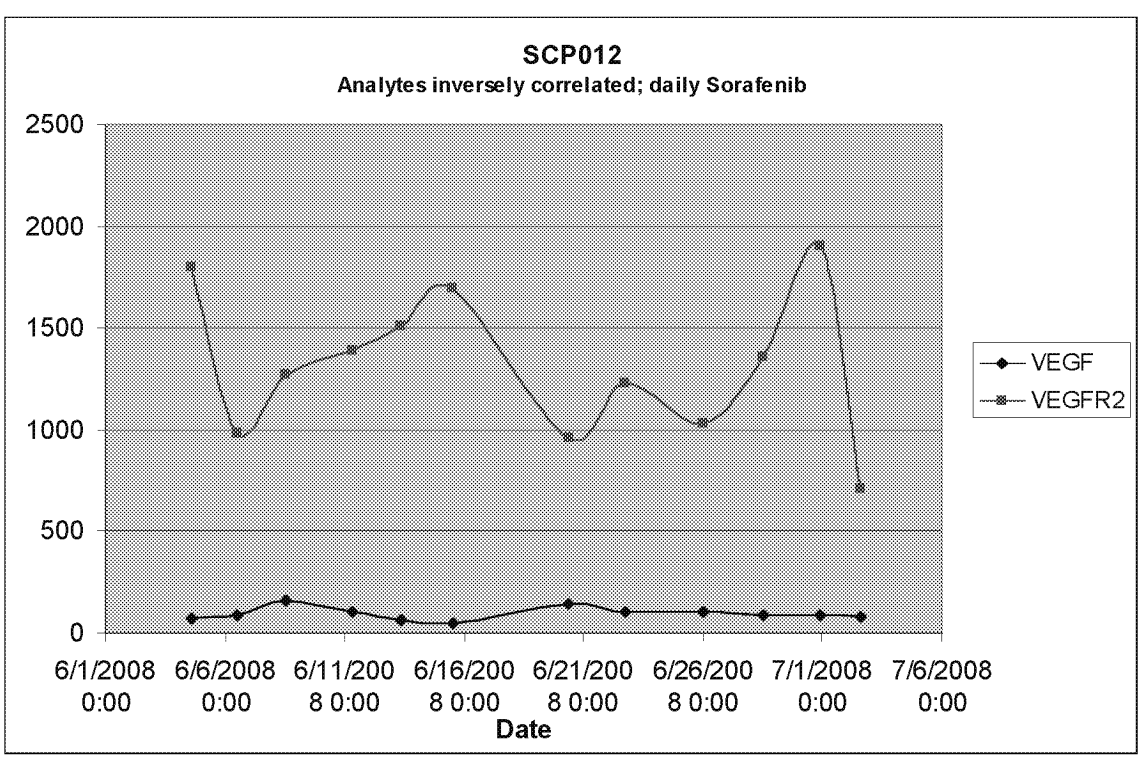
To showcase the ability to profile predictive correlations between treatment and response profiles, we selected data from two patients -- 14 and 12. Due to patient 14's clinic schedule (first figure below), we were able to collect data following multiple infusion dates, allowing limited statistical analysis to be performed that correlates analyte levels with treatment administration. The cross-correlation function (second figure below) looking at VEGF and VEGFR2 blood levels for patient 14 shows a positive correlation at a cadence of 3 data points. This coincides with the patient's weekly clinic visits during which the patient receives the Avastin infusions.

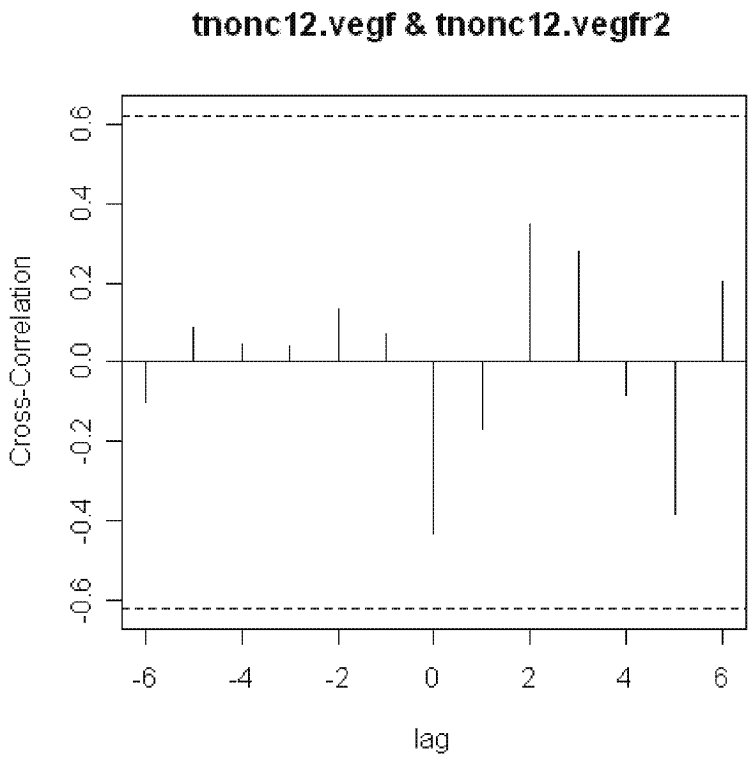


The change in rate of the parameters can be correlated to progress, seen again below in a correlation plot:



For patient 12 (first figure below), we observe an inverse correlation between VEGF and VEGFR2 blood levels. This suggests that the blood analytes behave differently with different drug treatments, pointing at distinct pathways of drug activity (second figure below).





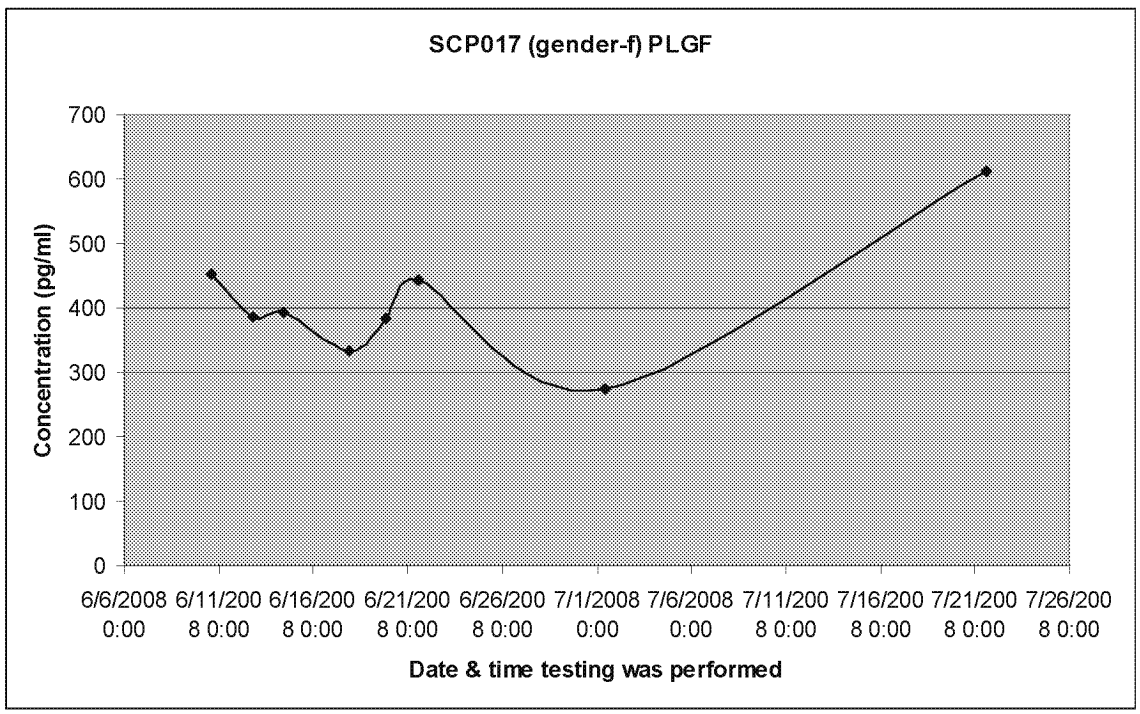
For most patients analyzed, the sample size and sample numbers did not provide sufficient statistical power to derive a statistically significant conclusion but some clinical endpoint measurements were accessible to correlate analyte vectors and their rates of change with time to the patient's progression and response to treatment.

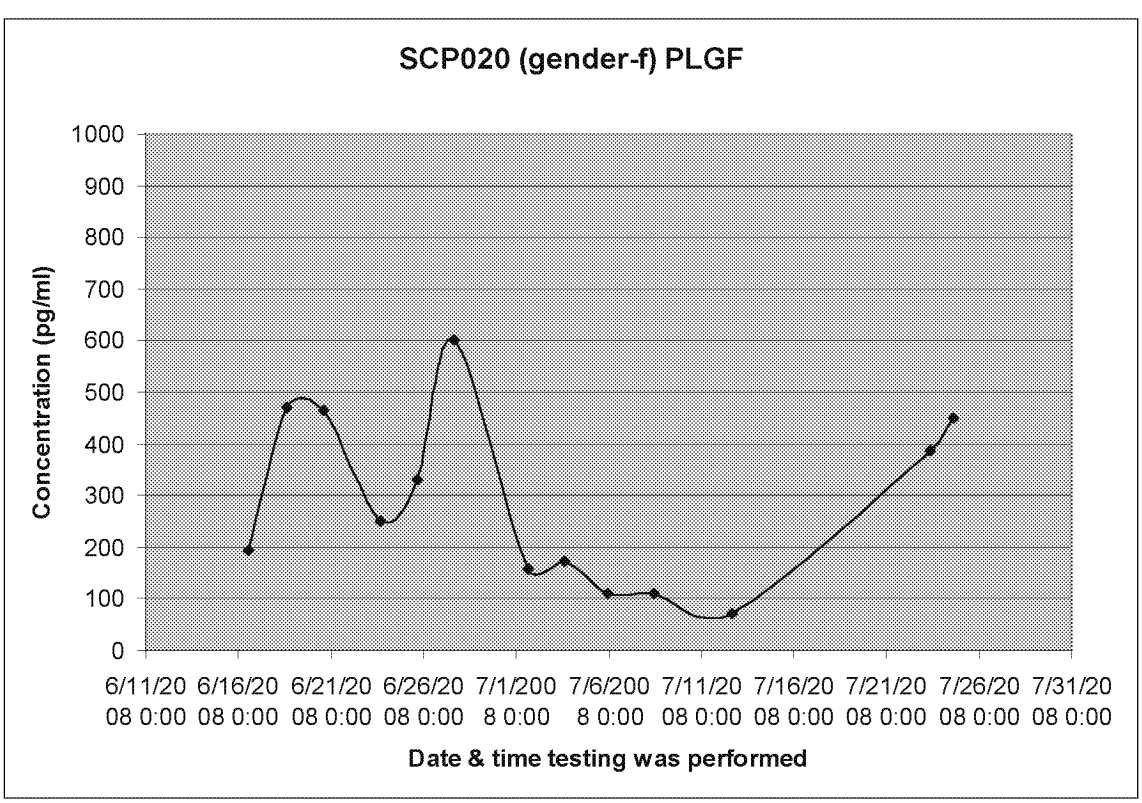
Patient average VEGF and VEGFR2 data by cancer type:

Patient ID	Cancer type	Main Treatment	Average VEGF (pg/ml)	Average VEGFR2 (pg/ml)
SCP001	Adenocarcinoma	Sutent	47.5	2592
SCP006	Breast Cancer	Avastin	2082	2662
SCP010	Breast Cancer	Avastin	2055	3040
SCP008	Breast Cancer	Sorafenib	98	1863
SCP021	Colorectal Cancer	Avastin	4677	3646
SCP027	Colorectal Cancer	Sorafenib	1093	4863
SCP029	Colorectal Cancer	Sorafenib	3612	5658
SCP003	Colorectal Cancer	Sutent	72	2798
SCP007	Colorectal Cancer	Avastin	3860	2350
SCP009	Colorectal Cancer	Avastin	1840	368
SCP022	Colorectal Cancer	Avastin	Patient dropped	N/A
SCP014	Colorectal Cancer	Avastin	1826	1634
SCP019	Colorectal Cancer	N/A	Patient dropped	N/A
SCP016	Colorectal Cancer	Avastin	3006	2143
SCP031	Colorectal Cancer	Avastin	13584	5463
SCP024	Colorectal Cancer	Sorafenib	255	1540
SCP028	Colorectal Cancer	Sorafenib	1274	6317
SCP023	Esophageal Cancer	Avastin	3145	2260
SCP030	Gastrointestinal Stromal Tumor	Sutent	889	2424
SCP012	Liver Cancer	Sorafenib	96	1253
SCP017	Lung Cancer	Avastin	3947	2111
SCP025	Melanoma	Avastin	5399	3294
SCP002	Neuroendocrine carcinoma	N/A	Patient dropped	N/A
SCP026	Ovarian Cancer	Sorafenib	Patient dropped	N/A
SCP020	Renal Cell Carcinoma	Sutent	368	883
SCP004	Renal Cell Carcinoma	Avastin	2316	1057
SCP011	Renal Cell Carcinoma	Avastin	3159	1911
SCP013	Renal Cell Carcinoma	Avastin	3908	770
SCP015	Renal Cell Carcinoma	Avastin	3031	1068
SCP018	Tongue Cancer	Avastin	1457	3074
SCP005	Unknown Primary	Avastin	3099	2980

As referenced, patients #2, #19, #22, #26 dropped out of the study for various reasons; therefore average values are not statistically significant for them.

For the patients in whom PLGF is consistently detectable we selected plots as shown below.





Patient monitoring times and quality of life by gender:

			Time of day when home monitoring was performed	Quality of life (as measured by on-screen survey)
Patient ID	**Cancer type**	**Gender**	**(on average)***	**(on average)***
SCP001	Adenocarcinoma	f	Morning	N/A (Survey was not yet deployed)
SCP006	Breast Cancer	f	Afternoon	7
SCP010	Breast Cancer	f	Evening	8
SCP008	Breast Cancer	f	Late Evening	7
SCP021	Colorectal Cancer	f	Noon-afternoon	8
SCP027	Colorectal Cancer	f	Afternoon	10
SCP029	Colorectal Cancer	f	Afternoon-Evening	not yet available
SCP003	Colorectal Cancer	f	Morning	N/A (Survey was not yet deployed)
SCP017	Lung Cancer	f	Evening	9
SCP026	Ovarian Cancer	f	N/A	N/A
SCP020	Renal Cell Carcinoma	f	Afternoon	6
SCP005	Unknown Primary	f	Afternoon	9
SCP007	Colorectal Cancer	m	Evening	7
SCP009	Colorectal Cancer	m	Late Evening	7
SCP022	Colorectal Cancer	m	N/A	8
SCP014	Colorectal Cancer	m	Morning	7
SCP019	Colorectal Cancer	m	N/A	N/A
SCP016	Colorectal Cancer	m	Evening	8
SCP031	Colorectal Cancer	m	Afternoon	not yet available
SCP024	Colorectal Cancer	m	Afternoon	9
SCP028	Colorectal Cancer	m	Evening	not yet available
SCP023	Esophageal Cancer	m	Morning	8
SCP030	Gastrointestinal Stromal Tumor	m	Morning	not yet available
SCP012	Liver Cancer	m	Afternoon	10
SCP025	Melanoma	m	Morning	9
SCP002	Neuroendocrine carcinoma	m	N/A	N/A
SCP004	Renal Cell Carcinoma	m	Noon-afternoon	10
SCP011	Renal Cell Carcinoma	m	Morning	9
SCP013	Renal Cell Carcinoma	m	Evening	10
SCP015	Renal Cell Carcinoma	m	Evening	7
SCP018	Tongue Cancer	m	Afternoon	5
* Actual time for each test point and diurnal variations of quality of life can be found online				

Patient compliance with optional on-screen questionnaire was approximately 86% (this number was calculated before the end of the study, therefore final compliance figures may change).

Patient clinical visit data by age:

Patient ID	Race	Smoking Status	Alcohol Consumption	Age	Weight (pounds)
SCP029	Caucasian	does not smoke now, positive history	None	36	179
SCP010	Caucasian	never smoked	monthly or less	45	165
SCP018	Caucasian	Smoke daily	None	45	181
SCP007	Caucasian	never smoked	None	46	213
SCP008	Caucasian	smoke occasionally	None	46	180
SCP002	Caucasian	never smoked	monthly or less	49	194
SCP016	Caucasian	smoke occasionally	monthly or less	49	167
SCP012	Caucasian	does not smoke now, positive history	None	53	190
SCP015	Caucasian	does not smoke now, positive history	None	53	174
SCP028	Caucasian	smoke occasionally	None	57	262
SCP001	Caucasian	does not smoke now, positive history	None	61	172
SCP027	African American	never smoked	None	62	167
SCP009	Caucasian	never smoked	None	63	221
SCP011	Caucasian	does not smoke now, positive history	monthly or less	63	305
SCP024	Caucasian	infrequent attempts (never developed a habit)	Every day	64	200
SCP023	Caucasian	never smoked	Every day	65	252
SCP005	Caucasian	does not smoke now, positive history	monthly or less	66	160
SCP021	Caucasian	smoke occasionally	monthly or less	66	198
SCP006	Caucasian	never smoked	monthly or less	68	163
SCP017	Caucasian	does not smoke now, positive history	Every day	69	112
SCP013	Caucasian	never smoked	monthly or less	71	230
SCP020	Caucasian	never smoked	None	72	101
SCP026	Caucasian	never smoked	None	73	132
SCP031	Caucasian	does not smoke now, positive history	None	73	134.5
SCP025	Caucasian	does not smoke now, positive history	None	77	184
SCP014	Caucasian	does not smoke now, positive history	monthly or less	78	217.5
SCP022	African American	never smoked	None	82	178
SCP030	Caucasian	never smoked	None	83	182

Sample of patient clinical blood work by patient ID:

Patient ID	Avg. % Lymphocytes	Avg. Heart Rate	Avg. Total Bilirubin	Avg. Systolic BP	Avg. RBC
SCP001	33.4	67.7	0.7	129.3	3.2
SCP002	34.1	55.0	0.3	161.0	4.3
SCP004	27.8	64.7	0.5	144.7	3.2
SCP005	36.4	75.0	0.2	127.5	3.9
SCP006	29.5	100.7	0.3	112.7	4.3
SCP007	24.0	73.0	0.3	131.3	4.4
SCP008	23.7	84.0	0.4	124.0	5.1
SCP009	25.0	71.5	0.7	133.0	4.5
SCP010	45.3	74.3	0.9	137.8	4.5
SCP011	28.6	82.0	0.6	135.0	4.8
SCP012	28.3	75.5	0.7	122.0	4.0
SCP013	31.1	72.0	0.7	137.0	4.2
SCP014	40.2	81.5	0.4	125.3	4.0
SCP015	35.4	78.3	0.3	147.0	5.0
SCP016	18.0	75.3	0.3	131.3	4.9
SCP017	20.7	89.3	0.4	114.0	4.2
SCP018	23.4	70.0	0.3	133.0	4.8
SCP020	17.9	60.7	0.4	146.0	3.7
SCP021	36.5	91.0	0.4	130.0	4.8
SCP022	23.5	93.5	0.7	123.0	4.0
SCP023	26.3	107.7	0.7	119.7	4.7
SCP024	18.8	83.0	0.7	139.0	3.7
SCP025	33.5	94.0	0.3	143.0	5.2
SCP026	34.6	110.0	0.4	125.0	3.7
SCP027	9.5	70.0	0.7	119.0	3.7
SCP028	21.2	98.0	0.8	125.7	5.2
SCP029	32.6	90.5	0.6	122.8	5.1
SCP030	42.3	72.0	0.4	137.0	3.7
SCP031	16.7	70.0	0.4	145.0	4.3

All individual patient data was profiled as it was generated on the Pfizer-specific secure portal at www.theranos.com; raw data can also be found in the attached excel spreadsheet.

Server and Data Transmission

Approximately 361 cartridge results and 203 optional home surveys from the field were successfully transmitted to the Theranos servers. There were less than 5% transmission errors that required the readers to either retry sending the data or wait until they had a better connection to send the data. All data gathered in the field was transmitted to the Theranos servers. For the first two patients, on-screen surveys were not available. The number of surveys received is smaller than the number of cartridge runs due to the above as well as patients filling only one survey for each of their clinic visits (even though they ran two cartridges per visit). Once surveys became available, each cartridge run also asked the user to complete an optional quality of life survey and compliance was very good.

Data distribution by transmission pathway to date		
Direct Internet Connection	Wireless-GSM	Traditional Phone line
5.6 %	90.7%	3.7 %

The only problem encountered with using GSM wireless phone technology was poor signal. The main reasons for poor cellular reception were: dense foliage, metal roofs and poor signal quality due to remote location. In one location (Stewart, TN), there was no cellular coverage at all; therefore the reader used the standard telephone line in order to connect to our servers and report data as it was gathered. All of this patient's logs were received by Theranos servers. In future studies, multiple network providers would be contracted for these areas.

Overall performance of the Theranos System based on Customer Care log:

The customer care line was available to patients 24 hours a day 7 days a week over the course of the entire study (July 07 to October 08). All calls were addressed professionally and all issues were resolved quickly, taking care to minimize the impact on patients and clinical staff.

The types of calls for which patients used the Customer Care line:

- Patient running low on supplies – the solution was to simply ship more of the needed supplies with overnight delivery to make sure patient had enough for the upcoming home tests.
- Patient not knowing how to turn machine on – the solution was to advise the patient over the phone on the procedures outlined in the setup sheet they received and to make sure they have the instrument up and running.
- Patient calling about scheduling an instrument pickup – solution was to schedule one of our representatives to pick up the machine or alternatively to have FedEx pick up the reader if patient was able to place it in the shipping container themselves.
- Patient called about blood transfer question – the solution was to advise the patient to leave the blood transfer device on a flat surface. If this solution was not sufficient, a new batch was shipped to make sure no capillary manufacturer defects were at fault.
- Patient called about instrument not recognizing cartridge – the solution was to ask patient to re-try and call back if problem persisted. The suspicion was that due to poor cellular signal the reader was unable to communicate, and by re-trying it would perform appropriately. There were no subsequent calls from patient.
- Patient called about instrument not being ready due to temperature – the solution was to ask patient to move reader away from A/C units and possible air currents. Patients had moved readers from initial installation location (one moved it to his RV, another into a really hot room) and the temperature extremes affected the readers' ability to maintain desired temperature. The Theranos readers are engineered to control temperature to eliminate variability associated with conventional assays.

The majority of systems deployed in the field performed their duties throughout the entire length of the patient monitoring schedule. One instrument had mechanical issues due to being misused; this happened during new personnel training at TNONC. The instrument was promptly replaced with a new instrument. Another failure occurred due to the instrument being damaged in shipping. Although it performed its functions properly for the majority of the patient's schedule it eventually malfunctioned and was also promptly (~24 hours) replaced. Yet another issue was related to the cellular carrier not identifying the instrument. To expedite the process and assure that the clinic

was adequately supplied it was decided to replace that instrument with one that was known to work. The problem was later resolved off-line.

Patient Compliance with protocol:

It is hard to estimate the patient compliance with the exact protocol due to the factors out of Theranos' control. In many instances patients re-scheduled their clinic visits and the new appointments were not communicated to us. At the onset of each patient's home monitoring they were provided with a tentative schedule which in many cases changed due to patient's need to travel or inability to keep scheduled appointments. With this in mind, we estimate that patient compliance with protocol was still very good, at approximately 96 % (measured as 80-120% of expected testing completed and received). Given the missing information, a much more accurate derivation would be possible.

Theranos System Assessment by Patients and Clinical Staff:

Patient end of study surveys were sent out to all participants. To date, 17 responses were collected from patients.

Summary of patients' assessment of the Theranos system:

- 88% of patients surveyed found the Theranos System easy to use; no patients found it "very hard" to use.
- 76% of patients found the written instructions to be very informative, with clear directions; 12% did not read instructions
- 91% of patients scored the training given by their Theranos representative either a 9 or 10 (10 being very good training)
- 76% of patients found the Theranos System takes little time to use
  (scores between 1 and 4 were tallied, with 1 = very little time and 10 = a lot of time)
- 100% of patients found the optional touch screen survey on the Theranos System easy to use, giving scores of either 8, 9 or 10 (10 = easy to use, 1 = hard to use).
- On a scale of 10 to 1 (10 = least painful, 1 = most painful), only one patient gave the blood drawing experience a score of less than 6. 59% felt almost no pain, scoring either a 9 or 10.
- 100% of the patients that responded to the survey gave Theranos Customer Support an excellent or very good rating
- For the majority of patients, the Theranos System worked very well. The major ways of solving the questions patients had were figuring it out on their own or calling the Theranos Customer Care line.
- In the follow-up survey, 100% of patients that responded said they received excellent or very good technical support over the duration of the study.
- Most patients said they prefer monitoring from home (scored 8 through 10) using the Theranos System; 25% were indecisive (scored 4 to 6) when asked whether they prefer going to the clinic or using the Theranos System; only two patients would rather monitor at the clinic.

From the interactions with clinical staff at Tennessee Oncology, the system was:
1. well received and
2. the client solutions team made a very positive impact on the clinical staff and patients through promptitude and professionalism.

Conclusions:

General:

1. The Theranos System performed with superior performance to reference assays while running in a complex ambulatory environment.
2. The existing Theranos support infrastructure enables on-demand home installation and patient training in extremely rural areas.
3. Patients preferred ambulatory monitoring to clinic visits and liked using the Theranos System.
4. Non-computer literate patients had no issues using the Theranos System.

Technical:

5. Inter-system accuracy is excellent and was demonstrated on a platform with superior performance specifications to reference methods.
6. Calibrations were updated with access to samples from the trial.
7. Good correlations were seen to various commercially available gold-standards.
8. Avastin does not block the Theranos assay.
9. The Theranos System can measure VEGF both free and bound to VEGFR2 and Avastin to better quantify dose-response.

Economic:

10. This 15 month study demonstrated the robust functionality of Theranos Systems. With this validation data, the technology can be applied to significantly cut costs and bring compounds to market faster:

11. More frequent sampling enabled better characterization of longitudinal time-series profiles of angiogenesis protein panels. More accurate insight of the change in rate of those panels over time enables significantly faster and earlier reads on efficacy dynamics.
    a. See efficacy dynamics trends and correlation to end-points in patient time-course profiles on the Pfizer web-portal at www.theranos.com.
12. Response profiles were seen in this study over 30 day intervals. Historically, these types of correlations have taken up to a couple years to demonstrate, or in some cases, were previously not demonstrable. This time gained facilitates rapid data generation for additions to a compendia and rapid label expansion of existing drugs. Equally, this approach can be used to fast-track approvals of key compounds and at the same time better optimize those compounds with better visibility to achieve the target product profiles.
    a. One of Theranos' pharma partners is publishing a report which estimates the increased time to market is valued at $1M per day – making every month quite substantial.
13. Through Theranos Systems, Pfizer will be able to reduce the number of sites, eliminate shipping costs for samples, processing costs, and analytical costs. Based on historical data, implementation of these systems will enable Pfizer to achieve ~50% cost savings over current study spending (previously demonstrated to be $15M of a $30M study budget). Equally, through better insight into pathway dynamics, Theranos is demonstrating the ability to reduce the number of patients required to show statistical significance in future studies by 30-50%.

File Produced in Native Format

Exhibit 4

Message

From: Gary Frenzel [/O=THERANOS ORGANIZATION/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=GFRENZEL]
Sent: 1/26/2010 11:42:33 PM
To: Danise Yam [dyam@theranos.com]
Subject: FW: Validation Report

Gary Frenzel
VP Assay Systems
Theranos
3200 Hillview Ave,
Palo Alto, Ca 94304

From: Gary Frenzel
Sent: Thursday, December 03, 2009 2:29 PM
To: 'constance.cullen@spcorp.com'
Subject: Validation Report

Hi Connie, I was asked to send this report on to you, and if you can forward to the proper people. After you and your group have an opportunity to go through it, let us know if you would like to arrange a phone conference to discuss the results. Thanks Gary

Gary Frenzel
VP Assay Systems
Theranos
3200 Hillview Ave,
Palo Alto, Ca 94304

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Theranos, Inc., 3200 Hillview Avenue, Palo Alto, CA, 94304

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Theranos Multiplexed Assay Panel Validation Report

Human IL-6, Human TNF-α, Human CRP (hs)

Contents

1. Introduction

The Theranos Assay System is a fully automated means for measuring concentrations of analytes (biomarkers, drugs) using immunoassay methodology. The system is comprised of instruments, single-use cartridges and a wireless communications link that conveys protocol information to the instruments from a Theranos Server and relays assay data to the Server for interpretation and distribution. Blood, plasma serum and control materials may be analyzed by the System. Calibration is performed at Theranos on a cartridge-lot-specific basis.

The System accepts a metered sample (25uL), from a proprietary sampling device or a pipette, dilutes it automatically to levels appropriate to each assay then executes an automated ELISA assay protocol. The protocol is selected from a set of released protocols available on the Theranos Server and identified by reading a bar code on each cartridge. The bar code is also linked to an assay lot-specific calibration algorithm. Assays are complete in about one hour.

Assays are typically grouped (multiplexed) in particular cartridges designed to monitor specific disease and therapeutic processes. For example, a cartridge designed to monitor acute and inflammatory processes measures IL-6, TNF-α and CRP. Schering-Plough is interested in use of the Theranos System and has sponsored a validation exercise at Theranos focused on the inflammatory marker cartridge.

In this exercise, many instruments (60) and three lots of cartridges were used.

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2. Storage and Use

Theranos cartridges should be stored in the original unopened packaging in an upright position at 4°C. Theranos instruments require no user maintenance or calibration. User prompts are provided on a screen which is part of the instrument.

3. Calibration

IL-6 and TNF-α assay calibration utilize recombinant analytes expressed in human-cell lines as calibration materials. These are reportedly more stable than recombinant analytes made in bacteria and more similar to the naturally occurring analytes. The CRP assay is calibrated with a human plasma-derived analyte. Theranos Systems assays recognize "natural", recombinant, and human-cell line expressed recombinant forms of IL-6 and TNF-α. Each lot of Theranos Cartridges is individually calibrated, the calibration equation is linked to the cartridge barcode and results are automatically computed on the Theranos data server. For this validation study, three cartridge lots were produced and calibrated.

NIBSC WHO Verification of Calibration

Exemplary assay responses are shown in Appendix A. Calibrations for IL-6, TNF-α and CRP were verified by testing the recovery of the current National Institute for Biological Standards and Control (NIBSC) World Health Organization (WHO) Reference Standards. The current WHO standard for IL-6 is NIBSC code 89/548 (recombinant protein produced in CHO cells with post translational modifications), for TNF-α NIBSC code 88/786 (a natural human protein derived from human BALL-1 cells), and for CRP NIBSC code 85/506 from human plasma. Spike recovery of all three WHO standards were within acceptable limits across the assay ranges as shown in the figures and tables below. Note that for the TNF-α assay we found low recovery (about 30%) of the WHO standard in a reference kit (R&D Systems Quantikine HS catalogue # HSTA00D, data shown in Appendix B). Therefore comparisons of sensitivity and slopes of assay correlations of results of the Theranos System with those of R&D Systems kits will show different results due to their respective calibrations. For example, the R&D Systems Assay would report a TNF-α value of 4 pg/mL when the Theranos Assay reports 12 pg/mL. If desired by a customer the Theranos System can be configured (in calibration algorithms) to provide results matching those of R&D Systems assays (or those of other predicate assay). It is our intention however to continue to perform primary calibration of Theranos assays using International Standard materials whenever possible since predicate assays not so calibrated may be subject to lot-to-lot variation in calibration.

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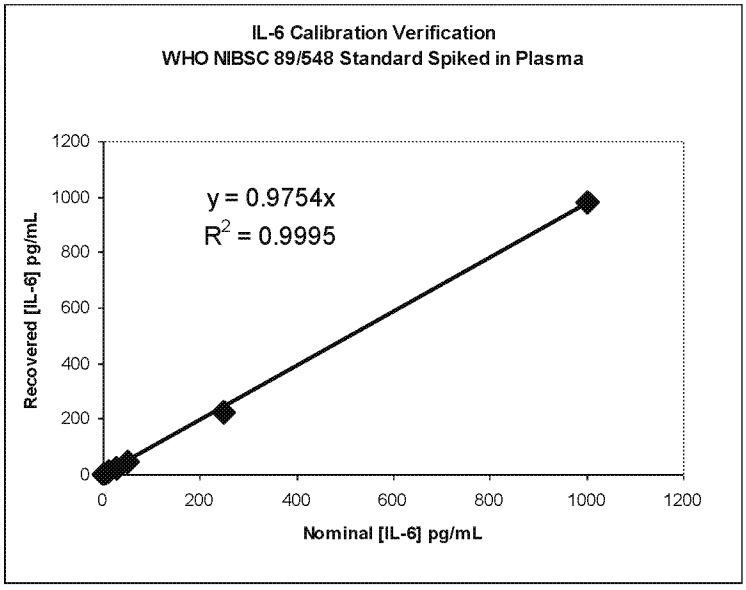

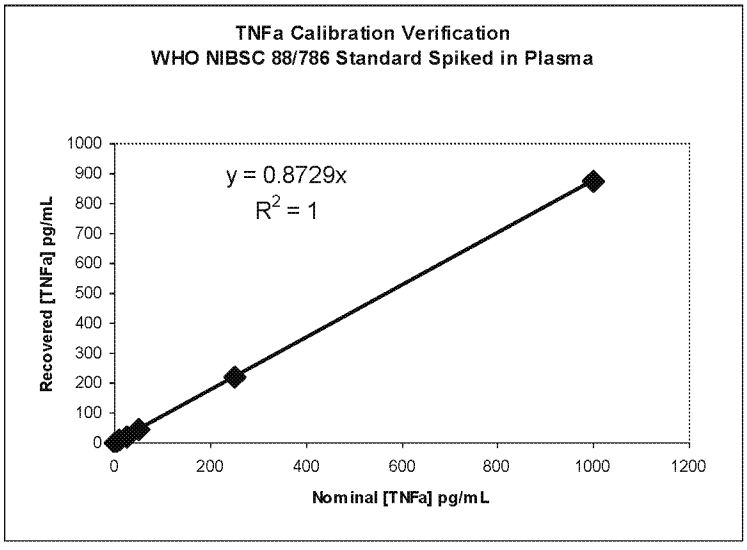

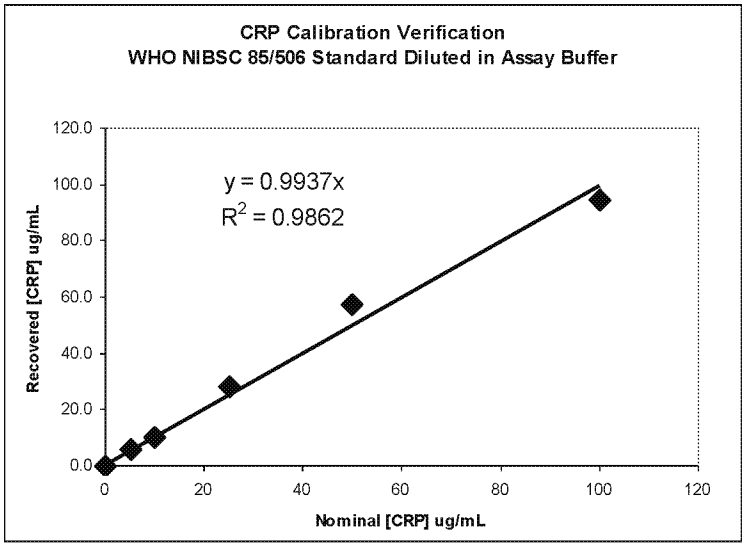

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Theranos Systems Recovery of IL-6 (NIBSC code 89/548) Spiked in Plasma n=3 cartridges, 3 instruments per level					
[IL-6] IU/mL	**[IL-6] pg/ml**	**Recovered [IL-6] pg/mL**	**CV %**	**Minus Endogenous**	**% Recovery**
100	1000	981.1	11	980.1	98
25	250	227.1	16	226.2	90
5	50	45.2	10	44.2	88
3	25	21.5	8	20.5	82
1	10	10.5	9	9.5	95
0	0	1.0	47	0.0	N/A

Theranos Systems Recovery of TNF-α (NIBSC code 88/786) Spiked in Plasma n=3 cartridges, 3 instruments per level					
[TNFa] IU/mL	**[TNFa] pg/mL**	**Recovered [TNF-α] pg/mL**	**CV %**	**Minus Endogenous**	**% Recovery**
46.5	1000	873.4	3	873.0	89
11.6	250	218.7	3	218.3	96
2.3	50	44.0	10	43.5	96
1.2	25	20.9	22	20.4	95
0.5	10	10.9	19	10.5	100
0	0	0.4	14	0.0	N/A

Theranos Systems Recovery of CRP (NIBSC code 85/506) in Assay Buffer n=3 cartridges, 3 instruments per level				
[CRP] IU/mL	**[CRP] ug/ml**	**Recovered [CRP] ug/mL**	**CV %**	**% Recovery**
98	100	94.6	2	95
49	50	57.4	18	115
24.5	25	28.1	15	113
10	10	10.2	14	102
4.9	5	5.7	20	114
0	0	0.0	30	N/A

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4. Range

Reportable ranges based on calibration to WHO standards determined for these assays are:

Assay	Low	High
IL-6	2 pg/mL	1000 pg/mL
TNF-α	4[1] pg/mL	1000 pg/mL
CRP	0.05 ug/mL	100 ug/mL

As shown below, all three tested lots support these ranges[2].

[1] Equivalent to 1 pg/mL in the R&D Systems assay calibrated using R&D Systems calibrators

[2] The lower limit of the reportable range of the TNF-α assay has been extended below the LLOQ so as not to restrict the reportable range too much. The LLOQ is higher than anticipated due to unexpectedly high imprecision of the assay in the cartridge lots used for validation compared with other cartridge lots used in pre-clinical work. We are presently investigating the root cause of this imprecision.

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5. Quantitation Limits

Assay calibrations and determination of Lower Limit of Quantitation (LLOQ) and Upper Limit of Quantitation (ULOQ) were performed and analyzed by proprietary software. Assay responses were fitted by a four-parameter equation and LLOQ and ULOQ determined according to FDA criteria. Calibrators were run in triplicate on three days (consecutive or non-consecutive) on 36 instruments for a total of nine cartridges per level, at 12 levels.

Summary of Calibration Analysis for three Cartridge Lots

Lot 2455142005	**IL-6**	**TNF-α**	**CRP**
LLOQ	1.3 pg/mL	6.3 pg/mL	0.05 ug/mL
ULOQ	1000 pg/mL	1000 pg/mL	150 ug/mL
Lot 2455146006	**IL-6**	**TNF-α**	**CRP**
LLOQ	1.3 pg/mL	6.3 pg/mL	0.05 ug/mL
ULOQ	1000 pg/mL	1000 pg/mL	150 ug/mL
Lot 2455156002	**IL-6**	**TNF-α**	**CRP**
LLOQ	2.3 pg/mL	6.3 pg/mL	0.05 ug/mL
ULOQ	1000 pg/mL	1000 pg/mL	150 ug/mL

Limits of detection (LOD)

The range in the Limits of detection calculated as 2*Signal SD/Slope of dose response (Δsignal/Δconc) are reported for the three lots of Theranos cartridges. Comparison data are also given for R&D Systems assays Minimum Detectable Dose "MDD" (which is equivalent to LOD). In addition to the calibration issue for the R&D Systems TNF-α assay discussed above which gives a four-fold lower limit for R&D Systems, we believe the calculation of MDD performed by R&D Systems may be compromised (falsely low) by the inability of any known spectrometer to report optical density to the required precision needed to support the calculated values.

The CRP MDD reported by R&D Systems is highly misleading since it represents the concentration in the assay rather than in the sample (which "must be diluted" according to their package insert prior to assay). Note that the Theranos assay uses a sample which is diluted 5000-fold. If we compare the actual sensitivity *in the assay medium* the Theranos value would be about 0.006 ng/mL.

Assay System	IL-6 (pg/mL)	TNF-α (pg/mL)	CRP (ng/mL)
Theranos	0.9 – 1.5	3.7 – 5.2	28 - 31
R&D Systems	0.02 – 0.11	0.04 – 0.19	0.005 – 0.22
R&D Systems[3]		0.16 – 0.76	

[3] Recalculated to reflect calibration to WHO standard material

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6. Precision and Accuracy

Plasma with low endogenous analyte levels was spiked with thee levels of the analytes were measured in 16 cartridges per level on 48 instruments. Recovery of the spiked analyte was good. Imprecision (% CV) ranged from 10 - 25 %. Note that the imprecision cited includes both instrument-instrument and cartridge-cartridge variance.

Spiked Plasma Samples (n=16 cartridges, n=48 instruments)

Nominal [IL-6] pg/mL	Recovered [IL-6] pg/mL	StDev	CV %	% Recovery
800.3	806.9	79.8	9.9	101
50.3	50.5	4.7	9.2	100
5.3	5.1	0.8	15.5	96
Nominal [TNFa] pg/mL	**Recovered [TNFa] pg/mL**	**StDev**	**CV %**	**% Recovery**
500.3	418.9	39.6	9.5	84
50.3	42.7	5.1	12.0	85
12.3	12.9	3.2	24.6	105
Nominal [CRP] ug/mL	**Recovered [CRP] ug/mL**	**StDev**	**CV %**	**% Recovery**
50.1	50.4	10.0	19.9	101
1.6	1.6	0.3	16.8	97
0.1	0.1	0.0	20.6	103

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7. Specificity

Assays were tested for cross reactivity and interference by the factors listed below, at high, mid and low analyte levels. Potential cross-reactants were selected based on package inserts of recognized predicate methods and added at levels deemed to be higher than those likely to be found in clinical samples. No significant cross reactivity or interference was observed for any of the assays by any of the tested factors at all analyte levels tested.

IL-6 Assay Specificity Test in Spiked Plasma (n=3 cartridges, 3 instruments per level)					
Substance	**[Test Substance] ng/mL**	**Target [IL-6] pg/mL**	**Recovered [IL-6] pg/mL**	**CV %**	**% Recovery**
Control	0	1000.3	1100.3	7.8	110
	0	90.3	95.8	16.6	106
	0	8.3	9.4	4.8	113
IL-1α	10	1000.3	939.2	2.9	94
	10	90.3	97.0	15.7	107
	10	8.3	9.0	6.9	108
IL-2	10	1000.3	1047.7	1.7	105
	10	90.3	86.7	9.4	96
	10	8.3	8.7	22.3	105
IL-3	10	1000.3	950.0	12.7	95
	10	90.3	91.9	4.6	102
	10	8.3	7.9	4.4	95
IL-4	10	1000.3	908.0	10.9	91
	10	90.3	79.9	16.7	88
	10	8.3	8.1	18.1	97
IL-6 sR	50	1000.3	914.9	18.0	91
	50	90.3	81.2	1.3	90
	50	8.3	8.0	29.0	96
IL-7	10	1000.3	895.0	10.0	89
	10	90.3	78.1	9.1	87
	10	8.3	8.2	9.4	99
IL-8	10	1000.3	927.8	9.7	93
	10	90.3	82.3	17.1	91
	10	8.3	8.4	17.6	101
IL-11	10	1000.3	897.5	12.5	90
	10	90.3	90.3	6.1	100
	10	8.3	7.9	2.2	95
IL-12	10	1000.3	837.6	8.4	84
	10	90.3	85.8	14.7	95
	10	8.3	6.8	18.1	82
CNTF	10	1000.3	900.6	8.4	90
	10	90.3	95.3	5.8	106
	10	8.3	8.9	22.4	107
G-CSF	10	1000.3	925.0	18.7	92
	10	90.3	90.2	12.8	100
	10	8.3	9.7	6.9	117

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IL-6 Assay Specificity Test in Spiked Plasma (n=3 cartridges, 3 instruments per level)					
Substance	[Test Substance] ng/mL	Target [IL-6] pg/mL	Recovered [IL-6] pg/mL	CV %	% Recovery
sgp130	1000	1000.3	895.5	17.0	90
	1000	90.3	88.6	2.0	98
	1000	8.3	9.4	3.2	114
LIF R	50	1000.3	895.2	2.8	89
	50	90.3	78.5	16.5	87
	50	8.3	8.9	19.8	107
OSM	10	1000.3	945.4	9.5	95
	10	90.3	77.1	10.0	85
	10	8.3	6.9	16.8	83
TNF-β	10	1000.3	919.6	8.6	92
	10	90.3	83.3	15.8	92
	10	8.3	9.4	7.8	113
IL-1β	10	1000.3	901.2	8.1	90
	10	90.3	85.7	17.6	95
	10	8.3	7.5	10.5	90
sTNF RI	10	1000.3	1025.2	9.2	102
	10	90.3	83.4	11.4	92
	10	8.3	9.4	16.5	114
sTNF RII	10	1000.3	963.3	13.8	96
	10	90.3	90.7	10.2	100
	10	8.3	9.3	21.0	112

TNF-α Assay Specificity Test in Spiked Plasma (n=3 cartridges, 3 instruments per level)					
Substance	[Test Substance] ng/mL	Target [TNFa] pg/mL	Recovered [TNFa] pg/mL	CV %	% Recovery
Control	0	900.3	883.7	4.1	98
	0	90.3	85.4	4.1	95
	0	8.3	8.3	40.4	100
IL-1α	10	900.3	849.1	5.5	94
	10	90.3	89.6	12.7	99
	10	8.3	8.8	16.0	106
IL-2	10	900.3	855.2	23.5	95
	10	90.3	90.8	7.9	101
	10	8.3	9.6	18.5	116
IL-3	10	900.3	836.5	23.5	93
	10	90.3	74.3	5.4	82
	10	8.3	8.2	29.2	98
IL-4	10	900.3	884.6	6.9	98
	10	90.3	89.5	8.5	99
	10	8.3	7.0	49.3	84
IL-6 sR	50	900.3	874.0	23.5	97
	50	90.3	77.8	13.8	86
	50	8.3	8.6	34.8	103
IL-7	10	900.3	871.9	6.3	97
	10	90.3	82.8	37.1	92
	10	8.3	7.6	22.9	91

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TNF-α Assay Specificity Test in Spiked Plasma (n=3 cartridges, 3 instruments per level)					
Substance	[Test Substance] ng/mL	Target [TNFa] pg/mL	Recovered [TNFa] pg/mL	CV %	% Recovery
IL-8	10	900.3	774.4	1.8	86
	10	90.3	83.4	13.5	92
	10	8.3	7.9	12.6	95
IL-11	10	900.3	901.8	1.5	100
	10	90.3	90.7	19.6	100
	10	8.3	9.3	36.8	112
IL-12	10	900.3	770.9	7.3	86
	10	90.3	77.4	15.8	86
	10	8.3	7.9	56.7	96
CNTF	10	900.3	920.1	6.0	102
	10	90.3	82.5	9.7	91
	10	8.3	8.7	18.9	105
G-CSF	10	900.3	1052.6	3.7	117
	10	90.3	95.6	20.7	106
	10	8.3	9.1	9.6	110
sgp130	1000	900.3	891.3	16.8	99
	1000	90.3	93.8	9.1	104
	1000	8.3	10.1	25.1	122
LIF R	50	900.3	781.5	20.7	87
	50	90.3	87.3	15.2	97
	50	8.3	9.1	12.1	110
OSM	10	900.3	862.1	10.6	96
	10	90.3	85.2	23.8	94
	10	8.3	7.4	54.1	89
TNF-β	10	900.3	804.0	24.7	89
	10	90.3	90.7	16.4	100
	10	8.3	7.7	32.3	92
IL-1β	10	900.3	900.0	17.3	100
	10	90.3	83.1	16.6	92
	10	8.3	8.3	33.1	101
sTNF RI	10	900.3	833.0	21.8	93
	10	90.3	86.4	19.5	96
	10	8.3	6.7	21.6	80
sTNF RII	10	900.3	801.3	8.9	89
	10	90.3	93.6	3.0	104
	10	8.3	8.2	14.2	99

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CRP Assay Specificity Test in Assay Buffer (n=3 cartridges, 3 instruments per level)					
Substance	**[Test Substance] ng/mL**	**Target [CRP] ug/ml**	**Recovered [CRP] ug/ml**	**CV %**	**% Recovery**
Control	0	50	53.0	16	106
	0	10	8.1	34	81
	0	0.75	0.7	13	91
Pentraxin-2/SAP	30	50	49.2	19	98
	30	10	8.9	9	89
	30	0.75	0.8	4	102
Pentraxin-3/TSG-14	10	50	40.6	7	81
	10	10	8.2	14	82
	10	0.75	0.7	5	100

8. Linearity

A plasma sample with low endogenous analyte levels was spiked with known levels of IL-6, TNF-α, and CRP then diluted serially with the unspiked plasma. All assays showed an appropriate linear dilution response across the dilution range (500 – 2000-fold). Data are tabulated and graphed below.

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Dilution Linearity in Plasma, Multiplexed Assays (n=3 cartridges, 3 instruments per level)

IL-6				
Spiked [IL-6] pg/mL	**[Expected] pg/ml**	**[Recovered] pg/mL**	**CV %**	**% Recovery**
950	950.5	958.1	7	101
	475.5	480.9	11	101
	238.0	256.1	18	108
	119.2	143.9	25	121
	59.8	62.3	3	104
	30.1	28.3	23	94
	15.3	13.3	34	87
	0.5	0.5	88	100

TNF-α				
Spiked [TNFa] pg/mL	**[Expected] pg/ml**	**[Recovered] pg/mL**	**CV %**	**% Recovery**
900	902.7	899.2	11	100
	452.7	461.5	9	102
	227.7	194.6	6	85
	115.2	105.0	11	91
	59.0	56.1	2	95
	30.9	30.6	4	99
	16.8	14.9	26	89
	2.7	2.7	14	100

CRP				
Spiked [CRP] ug/mL	**[Expected] ug/ml**	**[Recovered] ug/mL**	**CV %**	**% Recovery**
75	75.1	82.8	34	110
	37.6	35.0	0	93
	18.8	14.7	10	78
	9.5	9.1	12	96
	4.8	4.1	8	85
	2.4	2.4	7	98
	1.3	1.3	15	102
	0.1	0.1	29	100

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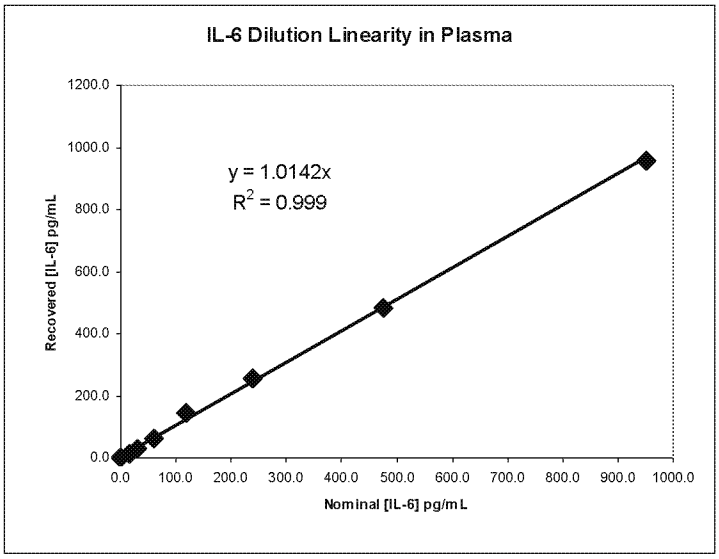

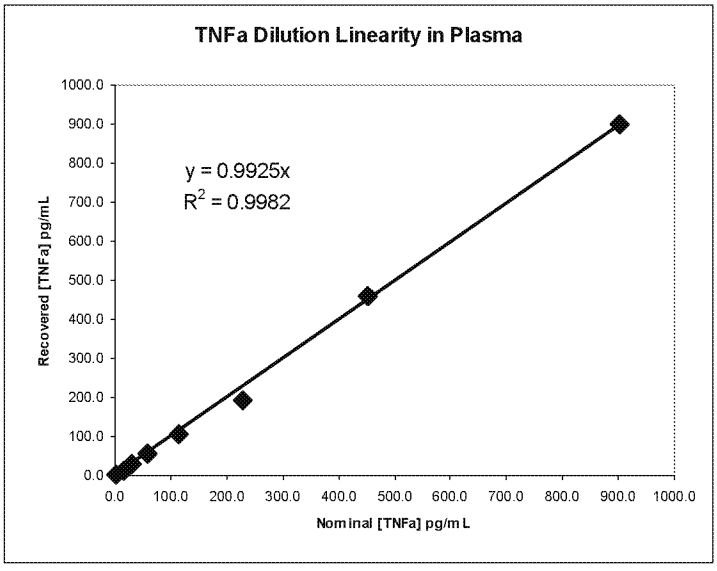

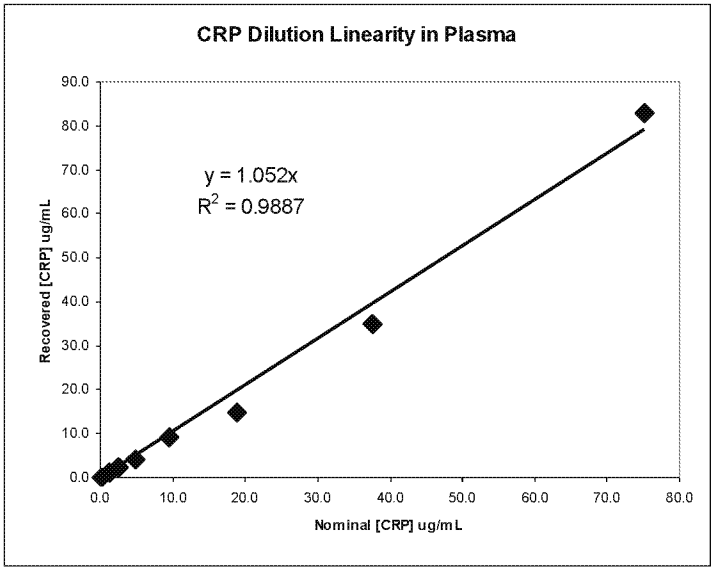

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9. Matrix Effects

Plasma or serum containing various potentially interfering factors or substances were spiked with known levels of analyte and the resulting recovery of the spiked analyte calculated after correction for endogenous analyte. None of the assays showed interference from icteric, hemolyzed, lipemic, or rheumatoid factor-positive samples as shown in the tables below

NORMAL SERUM Sample: PromedDx 10739123 (n=3 cartridges, 3 instruments per level)

Spiked [IL-6] pg/mL	Recovered [IL-6] pg/mL	CV %	Minus Endogenous	% Recovery
1000	1019.1	14	1015.82	102
250	224.9	4	221.58	89
50	47.7	14	44.42	89
25	25.3	6	22.01	88
10	12.6	9	9.29	93
0	3.3	43	0.00	
Spiked [TNFa] pg/mL	**Recovered [TNFa] pg/mL**	**CV %**	**Minus Endogenous**	**% Recovery**
1000	1019.1	14	1014.7	101
250	224.9	4	220.5	88
50	47.7	14	43.3	87
25	25.3	6	20.9	84
10	12.6	9	8.2	82
0	4.4	60	0.0	
Spiked [CRP] ug/mL	**Recovered [CRP] ug/mL**	**CV %**	**Minus Endogenous**	**% Recovery**
100	107.4	11	107.3	107
50	49.3	13	49.3	99
25	25.0	23	24.9	100
10	9.6	41	9.5	95
5	5.9	17	5.8	116
0	0.1	12	0.0	

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LIPEMIC SERUM Sample: Vital Products SFB8315 (n=3 cartridges, 3 instruments per level)

Spiked [IL-6] pg/mL	Recovered [IL-6] pg/mL	CV %	Minus Endogenous	% Recovery
1000	872.5	15	868.8	87
250	214.1	4	210.4	84
50	47.8	15	44.1	88
25	24.5	6	20.8	83
10	14.4	19	10.7	107
0	3.7	12	0.0	
Spiked [TNFa] pg/mL	**Recovered [TNFa] pg/mL**	**CV %**	**Minus Endogenous**	**% Recovery**
1000	965.0	17	962.8	96
250	230.8	15	228.6	91
50	56.6	40	54.4	109
25	25.4	13	23.2	93
10	14.8	14	12.6	126
0	2.2	32	0.0	
Spiked [CRP] ug/mL	**Recovered [CRP] ug/mL**	**CV %**	**Minus Endogenous**	**% Recovery**
100	119.4	36	119.1	119
50	54.2	40	53.9	108
25	24.4	25	24.1	96
10	10.4	9	10.1	101
5	5.8	15	5.6	111
0	0.2	12	0.0	

HEMOLYZED PLASMA Sample: Stanford W070509118560 (n=3 cartridges, 3 instruments per level)

Spiked [IL-6] pg/mL	Recovered [IL-6] pg/mL	CV %	Minus Endogenous	% Recovery
1000	1010.9	10	1010.0	101
250	274.6	13	273.7	109
50	51.6	2	50.7	101
25	26.8	11	25.9	104
10	10.5	12	9.6	96
0	0.9	41	0.0	
Spiked [TNFa] pg/mL	**Recovered [TNFa] pg/mL**	**CV %**	**Minus Endogenous**	**% Recovery**
1000	898.7	14	895.1	90
250	223.5	12	219.9	88
50	44.2	11	40.6	81
25	27.7	23	24.1	96
10	12.0	23	8.4	84
0	3.6	14	0.0	
Spiked [CRP] ug/mL	**Recovered [CRP] ug/mL**	**CV %**	**Minus Endogenous**	**% Recovery**
100	119.6	10	119.5	119
50	54.0	10	53.9	108
25	22.5	14	22.4	90
10	11.6	3	11.5	115
5	5.6	11	5.5	110
0	0.1	4	0.0	

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ICTERIC SERUM Sample: PromedDx 10739123 (n=3 cartridges, 3 instruments per level)

Spiked [IL-6] pg/mL	Recovered [IL-6] pg/mL	CV %	Minus Endogenous	% Recovery
1000	986.0	9	983.4	98
250	282.4	12	279.7	112
50	55.8	10	53.2	106
25	28.1	7	25.4	102
10	11.8	16	9.2	92
0	2.6	53	0.0	
Spiked [TNFa] pg/mL	**Recovered [TNFa] pg/mL**	**CV %**	**Minus Endogenous**	**% Recovery**
1000	969.8	5	967.4	97
250	219.6	22	217.2	87
50	45.0	11	42.6	85
25	24.5	5	22.1	88
10	10.6	22	8.2	82
0	2.4	17	0.0	
Spiked [CRP] ug/mL	**Recovered [CRP] ug/mL**	**CV %**	**Minus Endogenous**	**% Recovery**
100	109.5	8	108.4	108
50	41.7	80	40.6	81
25	29.6	14	28.4	114
10	10.1	11	9.0	90
5	6.4	19	5.3	106
0	1.1	3	0.0	

RHEUMATOID FACTOR POSITIVE SERUM Sample: Vital Products SFB7884
(n=3 cartridges, 3 instruments per level)

Spiked [IL-6] pg/mL	Recovered [IL-6] pg/mL	CV %	Minus Endogenous	% Recovery
1000	1118.0	10	1097.9	110
250	286.9	9	266.7	107
50	77.7	13	57.6	115
25	46.3	12	26.2	105
10	30.4	6	10.2	102
0	20.1	6	0.0	
Spiked [TNFa] pg/mL	**Recovered [TNFa] pg/mL**	**CV %**	**Minus Endogenous**	**% Recovery**
1000	1116.4	11	1112.3	111
250	228.9	5	224.8	90
50	48.0	13	43.9	88
25	24.2	13	20.1	80
10	14.0	20	9.9	99
0	4.1	27	0.0	
Spiked [CRP] ug/mL	**Recovered [CRP] ug/mL**	**CV %**	**Minus Endogenous**	**% Recovery**
100	110.9	18	105.8	106
50	49.1	17	44.0	88
25	34.2	29	29.0	116
10	15.5	9	10.3	103
5	10.9	11	5.7	114
0	5.2	28	0.0	

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10. Stability

The stability of component reagents for the present assays has been studied individually in lots made previous to the present study. The capture surfaces were stable for over 12 months, and the detection conjugates for at least six months. Stability of the integrated cartridges used for this validation report stored at 4C is being monitored and an updated report will include this data. Cartridges are initially assigned an expiry date of three months post manufacture.

Conclusions:

The Theranos IL-6, TNF-α, CRP assay multiplex has been shown to give accurate and precise results for three independently calibrated cartridge lots and all the many instruments used. Assay calibration has been established using WHO or other standard materials. Lower and upper levels of quantitation have been established. The assays are specific for their respective analytes when tested against potential cross reactants and are not interfered with by agents that may cause problems in immunoassays. Dilution linearity is satisfactory for all the assays. Assay cartridge stability studies are underway.

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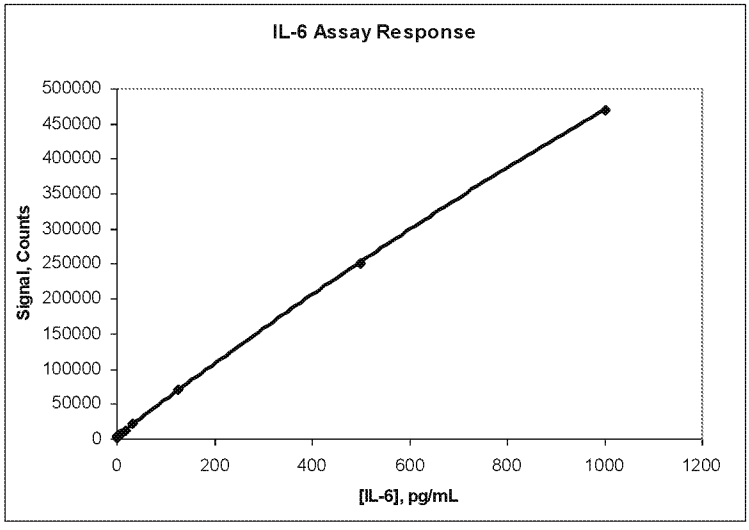
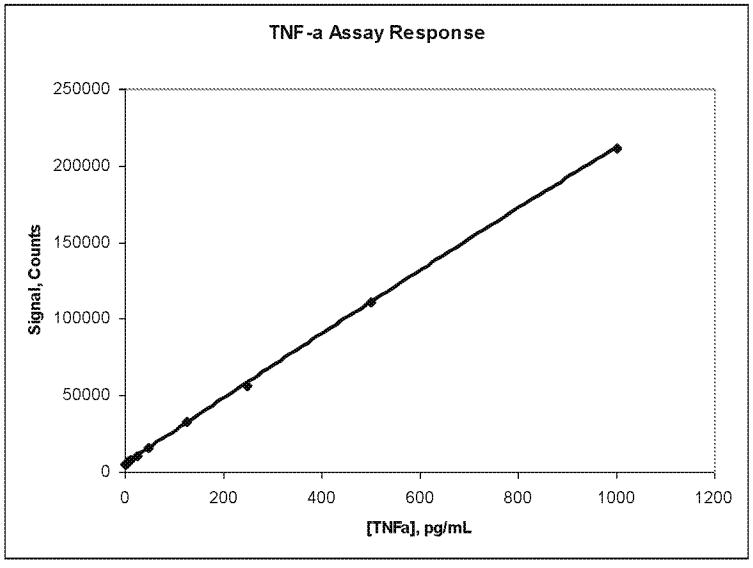
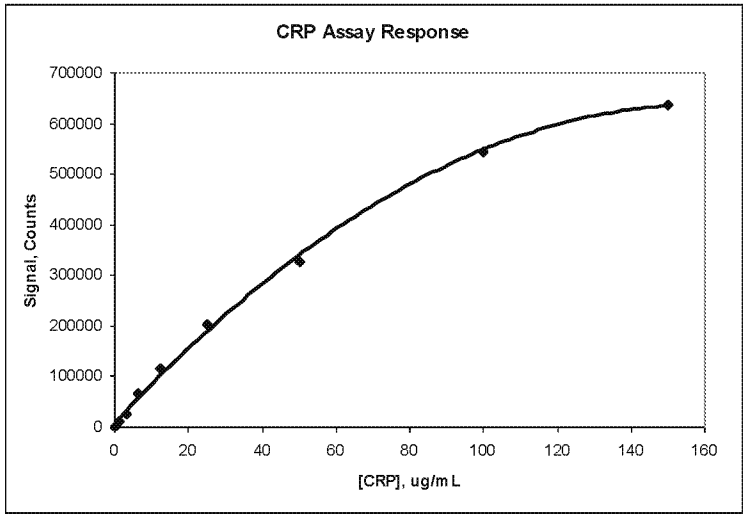
Appendix A







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Appendix B

Comparison of Theranos Systems TNFa Calibration to Other Available Commercial Methods

Plasma samples were spiked with WHO TNF-a Standard (NIBSC code 88/786) and run in Theranos Systems and in R&D Quantikine High Sensitivity Human TNF-α ELISA (catalogue # HSTA00D). The results are shown below.

THERANOS SYSTEMS Recovery of TNFa WHO Standard Spiked in Plasma

Nominal Spike		1pg/mL = 0.0465 IU/mL			
[TNFa] IU/ml	[TNFa] pg/ml	Calc. pg/mL	Minus Endogenous	Calc. IU/mL	% Recovery
0	0	5.2	0.0		
0.1	2.5	8.1	2.9	0.1	118
0.2	5	11.5	6.3	0.3	126
0.5	10	14.9	9.7	0.5	97
1.2	25	35.9	30.8	1.4	123
2.3	50	57.6	52.4	2.4	105
11.6	250	217.6	212.5	9.9	85
46.5	1000	1120.6	1115.4	51.9	112

R&D QUANTIKINE HS ELISA Recovery of TNFa WHO Standard Spiked in Plasma

Nominal Spike		1pg/mL = 0.0465 IU/mL			
[TNFa] IU/ml	[TNFa] pg/ml	Calc. pg/mL	Minus Endogenous	Calc. IU/mL	% Recovery
0	0	0.2	0.0		
0.1	2.5	1.0	0.8	0.04	32
0.2	5	1.8	1.6	0.07	32
0.5	10	3.2	3.0	0.14	30
1.2	25	7.3	7.1	0.3	28
2.3	50	15.0	14.8	0.7	30
11.6	250	83.6	83.4	3.9	33
46.5	1000	308.0	307.7	14.3	31

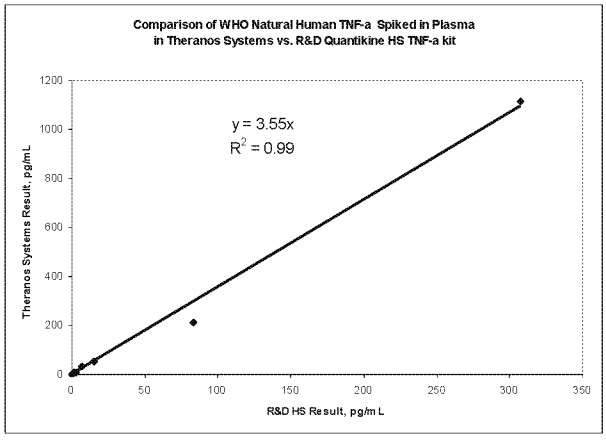

Exhibit 5

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Theranos Systems

Introduction
Theranos is transforming patient management, individual wellness, and the economics of health care delivery.

In doing so, Theranos has showcased a new economic model for pharmaceutical companies, exponentially increasing sales and rate of growth while cutting development expenses.

As the Theranos infrastructure begins to transform the way payors and physicians approach blood testing and reimbursement, the adoption of Theranos Systems in pharmaceutical companies is powering a radical new growth model for the pharmaceutical and biotech industry.

Return on Investment for Pharmaceutical Clients
Theranos' technology has been robustly validated over the last four years. Existing clients include AstraZeneca, BMS, Celgene, GSK, J&J Centocor, Mayo Clinic, Merck, Pfizer, and others. Theranos' direct-to-consumer home monitoring systems are currently being launched. In pharmaceutical clinical studies/programs, Theranos Systems have:

Accelerated trial timelines by an average of 18 months.
- Demonstrating meaningful dose-response and efficacy dynamics profiles in ~6 months where conventional infrastructure took two years and was still not able to generate equally predictive correlations.
- Existing customers value a six-month gain in time-to-market at $180 million to $540 million[1].

Reduced clinical operations costs by 50%.
- In addition to saving time, point-of-care ambulatory monitoring reduces the number of sites, as well as shipping, sample processing and clinical operations costs.
- Higher integrity field data and predictive models reduce the number of patients required in each clinical study by 25%.

Enabled realization of target product profiles that customers had not been able to achieve using the conventional testing and analytical infrastructure.
- Improved visibility into pathway dynamics
- Early reads on efficacy and safety dynamics
  - Established comprehensive longitudinal PK/PD profiles.
  - Characterized trends in the rate of change of key markers. (Conventional infrastructure obscures trends Theranos Systems elucidate.)
- Optimized development in ways previously not possible because of the biology complexities.
  - Enabled adaptive studies and development.
  - Salvaged assets that were about to be written off.
  - Rapidly enabled label expansion into key new patient populations and multiple indications.
  - Powered mechanistically driven cross-comparison studies for compound differentiation and reimbursement.

Enabled approval, reimbursement, and maximized use of key assets through drug-systems combinations now going onto the market together to optimize the benefit/risk profile of a drug on an *individual* patient basis. The individualized selection, treatment, monitoring and wellness counseling of subjects made possible through Theranos Systems is the foundation of a radical new growth model for pharmaceutical companies following the drug-device approach recommended by the Critical Path Initiative. The ability to comprehensively monitor blood-proteins and behavior in an at-home system enables pharmaceutical companies to overcome the clinical and economic limitations of what's currently known as 'personalized' – population-based medicine.

[1]Most recent estimates by an existing Theranos client value each day gained at 1-3 million dollars per day.

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The Theranos System

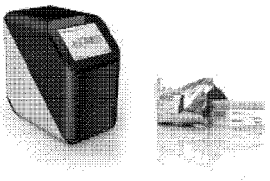
Theranos Systems are Theranos' proprietary, patented technology. The systems are becoming the center of healthcare in the home, making healthcare a home necessity in the same way that personalized computers made computing a home necessity.

For point-of-care technology to develop into a true individualized medical system (IMS) and make it a staple of patient care at the individualized level, significant breakthroughs were needed over the current state-of-the-art tools in the following domains:

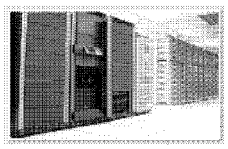
- Greater sensitivity, specificity, precision and accuracy of simultaneous assays
- Home protein analysis for time profiling
- Home drug analysis for exposure-response characterization
- Integration of data coming from various sources into electronic health records (EHR)
- Data modeling using Bayesian and other approaches
- Systematic, prompt feedback to the health care provider (HCP) and the patient
- Enabling early, adaptive and rapid decision making about healthcare utilization

The Theranos System was developed to address the aforementioned issues. Theranos Systems allow HCPs to monitor drugs, their metabolites, and relevant biomarkers from fresh whole blood samples in real-time at any testing frequency in a clinic, hospital setting or any point of care, including the home.

Theranos Systems process finger-stick blood samples at the point of care, wirelessly transmit data to relevant health care providers/clinicians, and can provide individualized and integrated content back to consumers to assist them in modifying behavior and establishing/achieving health and wellness goals. The user interface on the device is a graphical touch-screen, which links with an individual's mobile phone in real-time, providing each user with 'smart,' customized information.



Theranos' proprietary blood-analysis technology has made it possible to measure multiplexed combinations of drugs, proteins and other analytes in the home, and in doing so, characterize trends in disease progression and regression that were previously not seen. The ability to capture more comprehensive longitudinal time-series measurements is fundamental to better characterizing a patient's response to therapy.



When deployed, the information system allows for the integration and exploitation of information in a way previously not feasible. The home healthcare systems combined with the models in the information system enable accelerated clinical studies and realization of the target profiles of key assets.

In order to increase the value and coverage of marketed assets, compound-specific information characterized in clinical studies is being leveraged in the consumer environment. The information system allows for customized content to be deployed to device touch-screens and the associated mobile applications to enhance the value of a therapy.

The social networks which are rising around the mobile and home systems are proving to be powerful viral marketing channels.

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Theranos Systems are comprised of three integrated technologies and services.

1. Data infrastructure (for use across an entire pharmaceutical pipeline)
An information integration and exploitation infrastructure which permits:

- Data acquisition and storage of point-of-care results in real time.
- The integration of blood parameters and patient diary data with all other physiologically relevant information into the EHR.
- A central mathematical software program to:
  - Graphically visualize, help to interpret, and analyze all data in one place
  - Link any new information into a disease management system that then maps the information onto a probability space of clinical outcomes.
- The graphical display of clinically relevant and actionable information back to the HCP and/or the patient.

A customer-specific data integration and self-learning prediction and simulation engine to:

- Centralize all information in one repository.
- Automatically import data that exist in different formats (historical data, clinical studies, literature, patient records, etc.).
- Power models of patient response and disease pathophysiologies on integrated data sets.
- Constantly evolve and become increasingly predictive as learning algorithms process data from the field and literature without requiring human intervention.

2. Predictive and dynamic, multivariate, multi-dimensional models (customized for program-specific objectives) that map disease progression and regression
Algorithms

- Built-in pattern recognition tools characterize 'responder classes' and clinical outcomes.
- Probability analysis tools systematically account for uncertainty.
- Integrate physiological models with statistical analysis tools based on Theranos' proprietary time-series analysis.

Models

- Account for all relevant pathophysiologies and compounds' mechanisms of action
- Can identify relevant circulating parameters for patient monitoring and classification
- Are increasingly predictive to power future studies and decision making
- Simulate scenarios that answer 'what-if' questions and allow users to run queries themselves
  - Patient profiles
  - Trial protocols

3. Home Healthcare Systems (integrated point-of-care home and mobile monitoring systems that work for any combination of assays, including drug and protein analysis)
Devices – remote, portable patient care systems

- On-site, real-time, automatic processing of cartridges for blood analysis
- User interface designed for non-computer-literate subjects, allowing the patient to initiate the assays and to graphically enter a variety of relevant environmental information, such as comprehensive patient diary, behavioral, and psychological information, through touch-screens embedded in the device
- Two-way communication system from the instruments to HCP/clinicians, mobile phones, and back to patients with relevant content, messages, and health information
- Blood and environmental data is automatically (wirelessly) transmitted into models in real time.
  - Fully exploit all data (every IIT or pivotal trial increases the predictive value of the models).
  - Characterize dose-response, efficacy and safety dynamics faster and more accurately.

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Cartridges – disposable cartridges pre-loaded with chemistries to simultaneously measure multiplexes of proteins and other analytes from ~20µL whole blood finger-stick

- Cartridges can be customized to measure any combination of drugs and biomarkers together to map indicators/trends through comprehensive longitudinal PK/PD profiles of subject status.
- Rapid characterization of rate-of-change in key markers and trends (through more frequent monitoring than possible using central labs) yields predictive insight into clinical outcomes far earlier than more traditional radiologic and clinical end-points, resulting in earlier go/no-go decisions across multiple indications.
- Assay precision and trend generation capabilities reduce required patient numbers.
- Standardized analytical platform can be used across all sites.
  - Reduce variability of data between sites.
  - Improve quality of data by avoiding issues with analyte decay rates and sample processing.
- Drug-specific cartridges complement wellness/disease-specific cartridges that are being launched by Theranos direct to consumers and physicians.

Mobile Applications – transmission of individualized content to 'smart,' automated 'counselors' on device touch-screens and users' mobile phones to assist with behavior modification and increase compliance with therapy

- Theranos' proprietary algorithms enable the correlation of blood data to efficacy dynamics profiles, behavior, lifestyle, diet, and side-effects.
- Truly individualized content is selected to help people change their lifestyles in a sustained way, through the integrated use of the back-end algorithms, models, and data in the data infrastructure.
- Content is based on data for patient 'classes,' which recognize physiological and psychological pre-dispositions as well as local socio-environmental influences.
- Applications link users through social networks, where success stories compound through the combination of each tailored home health system with a given therapy.

Theranos' Client Services include:

Customization

- Devices
- Cartridges
- Informatics Systems
- Web portals
- Mobile applications for specific assets

Study Planning

- Biomarker selection

Support

- 24x7 live international call center
- New Information System features for in-person training of all site and where applicable, at-home device installations and training for patients
- Maintenance of information systems and all web and mobile applications

Regulatory Filings

- Compound-specific cartridges

Distribution of the systems to consumers, physician's offices, and pharmacies

- Sale and distribution of devices and cartridges
- Reimbursement for devices and cartridges

Marketing through the creation of Theranos' product-specific mobile, device and web-based wellness social networks

Exhibit 6

FW: STRICTLY CONFIDENTIAL - Pharmaceutical documents

From: Elizabeth Holmes <eholmes@theranos.com>

To: Sunny Balwani [redacted]

Date: Wed, 12 Aug 2009 10:15:31 -0700

Attachments: TPS Introduction 28Jul09FinalApproved.ppt (692.22 kB); TPS Executive Briefing 5Aug09FinalApproved.doc (428.54 kB); TPS Case Studies 28Jul09FinalApproved.ppt (3.79 MB); Theranos Systems Pharmaceutical Introduction 4May09FinalApproved.doc (864.26 kB); Theranos Impact on Cost Savings, Revenue and Growth for ELISA PK 4Jun09FinalApproved.doc (146.43 kB); Theranos Impact on Cost Savings, Revenue and Growth for MassSpec PK 4Jun09FinalApproved.doc (147.97 kB); Theranos Comparison to alternative modeling tools24NovFinalApproved.doc (92.16 kB); Assay Development, Validation, and Selected Clinical Results 24Jul09FinalApproved.ppt (5.8 MB); Assay Validation - GIP 12DecFinalApproved.doc (96.77 kB); Assay Validation - GLP-1 12DecFinalApproved.doc (96.77 kB); Assay Validation - Human IL-6 12DecFinalApproved.doc (111.62 kB); Assay Validation - Human TNF-a 12DecFinalApproved.doc (97.28 kB); Theranos Assay Library (CDA required) 28Jul09FinalApproved.doc (86.02 kB); Theranos Assay Library (no CDA required) 28Jul09FinalApproved.doc (72.19 kB); Joint Study Development and Management 8Apr09FinalApproved.doc (99.33 kB)

Please let me know if you have any difficulty opening any of these files.

Thanks,
Carolyn

Exhibit 7

Message

From: Elizabeth Holmes [/O=THERANOS ORGANIZATION/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=EHOLMES]
Sent: 12/15/2009 7:32:42 PM
To: thomas.breuer@gskbio.com
CC: Sunny Balwani [sbalwani@theranos.com]
Subject: Follow up to our meeting

Dear Thomas,

It was great to meet you.

In follow up to our conversations, I have attached three documents to this email.

The first is a consolidated summary of the GSK infrastructure we've designed in follow up to our interactions with people on the corporate side in information systems and strategy. We took ten slides on the applications in Biologicals and added them to the end of that summary – slides 28-38. The first slide highlights the ability to use the existing surveillance infrastructure to rapidly test the efficacy of existing vaccines against drifted strains of influenza virus using Theranos' strain-specific real-time antibody tests and the formulas we've established for the relationship between dose, antibody levels, and clinical outcomes.

The second is a copy of the validation report from the GSK staff who tested Theranos technologies in RTP. As you can see in that attachment, GSK's lab Director concluded that "Theranos Systems eliminate the need for a lab." The report shows the ability to get better sensitivity and real-time data using Theranos.

The third is a copy of a case study on Theranos' analytics also reviewed by GSK staff in detail during their due diligence process. This review focused on the ability to improve probability of success of realizing a target product profile with Theranos analytics. The case study details another company's use of Theranos analytics in registrational studies where the system increased POS from 15-80% and saved 18-24 months in clinical development timelines.

The Theranos Solution is a fully integrated and automated system for data capture, analysis, and care delivery. The data capture capability in combination with the predictive analytics capability has been the key to our success in accelerating development timelines.

We are very much looking forward to following up with your clinicians in Philadelphia. Is there a convenient time this week we could meet or arrange a video-conference? Please let us know how best to follow up.

Kind regards,
Elizabeth.

Elizabeth Holmes
President and CEO
Theranos, Inc.

Tel: 650.470.6111
Fax: 650.838.9804

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GTS

GSK's Strategic Enterprise Infrastructure

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Contents

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Introduction to Theranos, Inc.

Theranos is a Silicon Valley-based healthcare company founded in 2003.

- Theranos provides fully customized solutions that impact a diverse range of stakeholders in health care by providing actionable information far earlier than historically possible
- Our current and past clients include 9 of the top 15 major pharmaceutical companies, midsized bio-pharmas, prominent research institutions and U.S. and foreign government health organizations

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About Theranos

Founder and CEO Elizabeth Holmes left Stanford University to start Theranos around her patents for next-generation healthcare systems. She has built the company from inception to rapid commercial growth today.

Vice Chairman Sunny Balwani joined Theranos after leaving Microsoft to successfully build and sell his own company for over $400M

Other Management Team Members:

- Dr. Channing Robertson, Dr. Seth Michelson, Jodi Sutton, Dr. David Lester, Dr. Marc Thibonnier

Theranos' investors and board members include, amongst others:

- Donald L. Lucas, the first venture capitalist in Silicon Valley, and a legend behind many of today's Fortune 500 companies
- Larry Ellison, Founder and CEO of Oracle Corporation
- Bob Shapiro, former CEO and Chairman of Monsanto and Pharmacia Corporations (now Pfizer); former director of NYSE, Citibank, and other major corporations
- Draper Fisher Jurvetson; ATA Ventures (spin-out of Institutional Venture Partners)

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Theranos & GSK

- GSK completed a comprehensive validation of Theranos Systems in 2008
  - Validation was independently conducted run by GSK staff at RTP
  - Validation concluded "Theranos Systems eliminate the need for a lab"

- Over the past four years, leads from all three business units across all therapeutic areas have evaluated and expressed interest in the Theranos infrastructure

- Theranos and GSK have a fully executed MSA

- Integrated architecture of Theranos infrastructure requires adoption at top corporate levels

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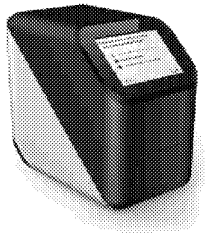
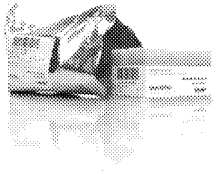
Theranos Infrastructure Technologies

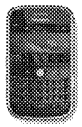
Theranos Field Systems



Devices

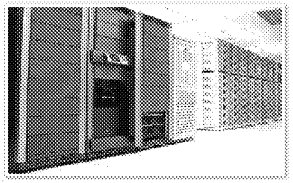


Cartridges

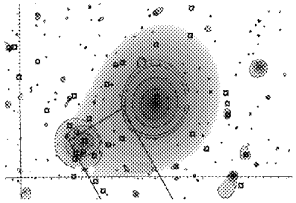


Mobile Applications –
Ex. the Health Assistant

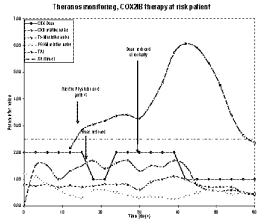
TheranOS – Theranos Operating System



Data Infrastructure



Models and Algorithms



Decision Support Applications
– Ex. Virtual Studies

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GTS

- GTS is a fully integrated, enterprise wide health data capture (including blood testing), analysis and care delivery solution
- Accelerates clinical development timelines, improves probability of success (POS) of realizing each target product profile, and increases physician and patient adoption (increases sales)
- Comprised of Theranos Field Systems and the TheranOS
  - Integration of technologies and more frequent sampling identifies predictive signatures that have not been possible to characterize using the conventional analytical infrastructure (movie v. snapshot) to better and more rapidly characterize efficacy and safety
  - Infrastructure is self-learning and is refined with every new data point collected across any business unit
  - Provides predictive decision support tools for clinicians
  - Provides actionable, “smart” content back to patients to facilitate behavior modification
  - Data Collection, Analysis & Surveillance Infrastructure in emerging countries becomes care delivery infrastructure

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Contents

- Background
- GTS ROI
- GTS Deliverables
- GTS in Biologicals

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Economic Impact for GSK

- Accelerate Clinical Development/Trial Timelines
- Improve Probability of Success of Realizing Target Product Profiles
- Increase Physician and Patient Adoption – Increase sales

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Economic Impact for GSK

- Accelerate Clinical Development/Trial Timelines
  - Elimination of Logistical constraints (shipping samples, analyzing data, bringing patients into clinics, recruiting patients without knowing their response profiles, etc.) and
  - Faster, more integrated studies (adaptive trials and decision making)

  cumulatively reduce development timelines by (~3) years to facilitate earlier filings.

- Theranos' large pharmaceutical clients have valued the fully loaded cost of each day gained in time to market at $1M/day

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Economic Impact for GSK

- Improve Probability of Success of Realizing Target Product Profiles
  - 5x improvements in probability of success for each asset
  - Salvage assets and improve labels (more first line therapies)
  - Realizing the improvement in attrition rate across the entire portfolio versus just one compound continually reduces the fully loaded cost of R&D
- 5x improvement in probability of success correlates with greater than 10% ROI on the total investment into a compound, averaging greater than $200M/asset

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Economic Impact for GSK

- Increase Physician and Patient Adoption
  - Evidence based guidelines for starting/stopping/re-starting therapies to increase physician comfort with prescribing
  - Rapid publications for expanded use – new indications and amelioration of safety concerns
  - Improved care delivery through individualized feedback tools and better access to medicines through Theranos' decentralized testing infrastructures (in pharmacies, through health ministries, etc.)
- Increase sales by several multiples over current adoption/projections

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Return on Investment

- The value of GTS lies in the fact that it is a fully integrated solution for data capture, integration, analysis, (and therapeutic delivery) across business units.
- The integrated solution provides compounding ROI over any particular business unit or drug-specific component.
- The key to significant ROI on GTS is programmatic deployment, which yields short term cost savings against the initial customization investment in addition to longer term ROI measured in terms of time saved and improved POS of realizing the target product profile for each asset.

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Immediate ROI: Executing on Healthcare Diversification Strategy

GTS is the vehicle for execution of GSK's strategic priorities and realization of the associated impact to earnings and growth

- Accelerated timelines … simplifying GSK's operating model
- Improved POS … delivering more products of value
- Increased adoption … growing a diversified global business

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Theranos is the only company with full integration between sample analysis and analytical capabilities

GTS integrates patient sample analysis with sophisticated analytical capabilities to increase R&D ROI.

Capability	Clinical Trial Simulator	Physiological Modeler #1	Physiological Modeler #2	Central Lab	CRO	theranos
Patient recruitment					✓	✓
Investigator/site mgmt					✓	✓
Sample handling				✓	✓	✓
Sample analysis				✓	✓	✓
Data management	✓	✓	✓		✓	✓
Basic analytical package ▪ PK/PD modeling ▪ Clinical trial simulation	✓	✓	✓			✓
Physiological model		✓	✓			✓
Dynamic learning models and real-time data acquisition						✓
Clinical study report					✓	✓

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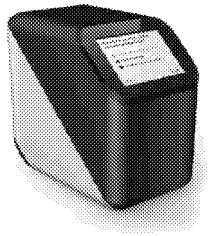
Theranos Field Systems



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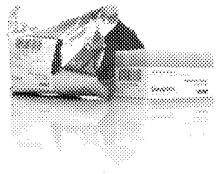
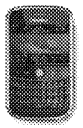


Cartridges



Mobile Applications –
Ex. the Health Assistant

- Measure whole blood analytes from a finger stick in real-time at any desired point of care (home, clinic, or mobile units)
- Simultaneously collect behavioral and lifestyle information through intuitive graphical touch screen interface
- Data from each device automatically and securely transmitted to TheranOS in real-time through cellular network
- Actionable information sent back to devices and applications (i.e., the Health Assistant, Virtual Studies Application)
- Point-of-care analysis of fresh whole blood eliminates conventional testing infrastructure issues, such as:
  - Analyte decay rates
  - Volumes of blood and frequency of blood draws
    - Decreases sample volume by 98%
    - Sampling schemes no longer restricted
  - Cost and logistics of sample shipments

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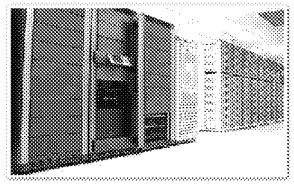
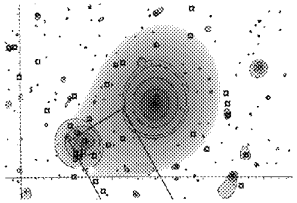
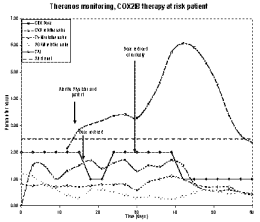
TheranOS



Data infrastructure



Models and Algorithms



Applications – Virtual Study

- Data Infrastructure
  - Automatically imports data from any desired source.
  - Translates it into one standardized format.
  - Self-learning data engine
- Models
  - Dynamically models the integrated data sets in real-time
  - Fully integrated and inter-connected physiological, statistical, and epidemiological system
  - Characterize each compound's mechanism-of-action.
  - Characterize all pathophysiologies associated with realizing each compound's target product profile
- Customized Applications
  - Clinical trials simulation
  - Adaptive trials management, in compliance with existing regulatory guidelines
  - Accessed through secure online web portal

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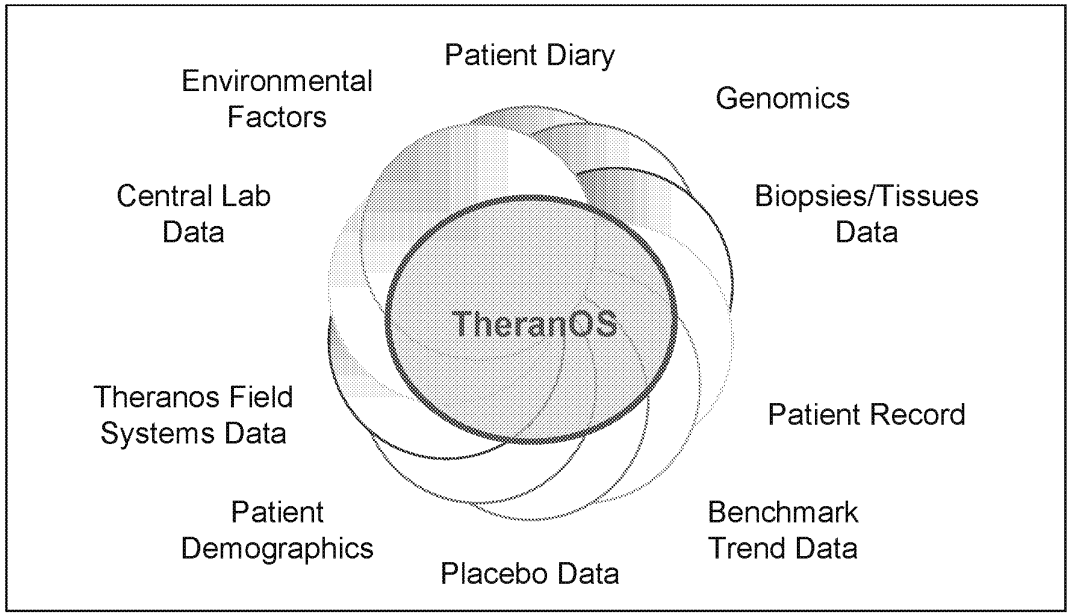
TheranOS: Proprietary Data Integration, Translation

- Proprietary import tool on web portal allows for automatic importation and standardization of data from all clinical databases.
- All data is automatically integrated with Theranos Field Systems data, centralized, and passed through predictive models.



TheranOS Data Infrastructure

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GTS Architecture Drives Deployment Plan

- A cornerstone of GTS' architecture is the inflammation engine.
- The central role of inflammation in the disease process and tissue damage/repair, allows one to apply the GTS infrastructure across various therapeutic areas and business units.
- Deployment of a customized inflammation platform provides the ability to rapidly integrate data from different pathophysiological states for predicting and establishing novel therapeutic indications.
  - GTS engine learns from every new data point and models become increasingly predictive -compounding predictive power
- Drug-specific models and cartridges are built on GTS' pathway architecture to conform to existing business unit structure.
  - TheranOS allows for data integration & exploitation across a broad range of existing data capture tools.

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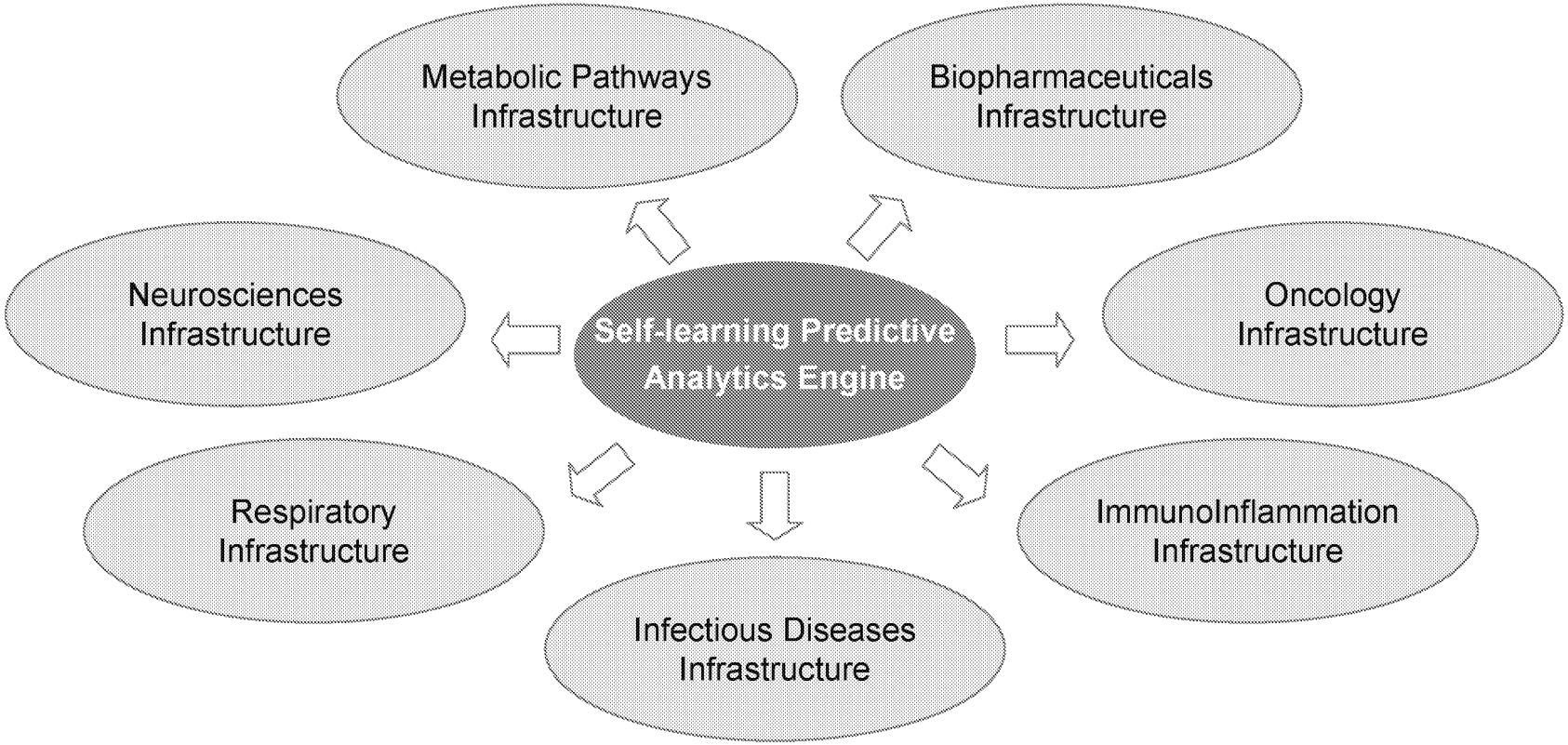
Rapid Customization of GTS: Therapeutic Area Infrastructures



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Decision support applications:

TheranOS Software for each Therapeutic Area:

- Probability Mapping Application
- Health Assistant
- GTS Assistant
- Adaptive Studies
- Ontologies
- Predictive Signatures
- Biomarker Identification Application (BIA)
- Virtual Study Application
- Others

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Data Collection Library & Care Delivery Tools:

For each therapeutic area:

- Cartridge tests – libraries of ~250 tests per disease area
- Device touch-screen software applications and embedded sensors – blood pressure, weight, others
- Mobile phone applications

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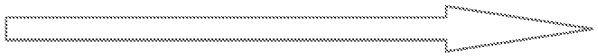
Rolling infrastructure set-up



Data Infrastructure

Inflammation Engine

7 Therapeutic Area Infrastructures

Customization and activation of base GSK data infrastructure and learning engines followed by rolling set up of 7 therapeutic area infrastructures

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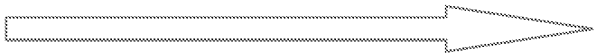
Rolling infrastructure set-up



Data Infrastructure

Inflammation Engine

7 Therapeutic Area Infrastructures

- Biologicals
- Prescriptions
- Consumer

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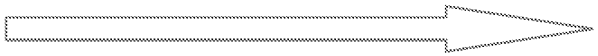
Rolling infrastructure set-up



- Biologicals: Influenza (vaccine) → Oncology → Others
- Prescriptions: Unprecedented Early Development Compounds, REMS, LpPLA-2 → Early Development, Phase III, Phase IV & Post marketing studies
- Consumer: Weight loss (alli) → Smoking Cessation → Others

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Deployment of GTS

- Customization, Installation, and License of enterprise infrastructure
- Deployment of consumables for studies
- License expansion – Deployment of additional drug-specific models/consumables

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GTS in Biologicals

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Rapid Validating Efficacy of Existing Vaccines Against Drifted Strains of Influenza Virus

- Theranos characterized relationship between dose, clinical efficacy, and antibody titers to influenza strains on its validated point-of-care systems.
- Assays identify functional, strain-specific antibodies from a finger-stick of fresh whole blood.
- Once deployed in a clinical study, patients could be immediately challenged with the actual virus and followed for 2+ weeks to assess whether the existing vaccine is efficacious.
- If not, the same infrastructure could be used to rapidly assess optimal dose and efficacy of a new vaccine.

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Influenza Surveillance Infrastructure

Real-time development and deployment of antibody, cytokine, and efficacy/safety marker measurements from finger-stick of blood /nasal swab run on point-of-care device

- Characterize velocity of antibody decay
- Accelerate development of new vaccines to mutations
- Quantitatively characterize efficacy and safety profiles to ameliorate concerns and differentiate GSK vaccines
- Guide optimal administration of vaccines
- Provide real-time measurement of efficacy and immunity

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Influenza Surveillance Infrastructure

Modeling and simulation of efficacy and safety dynamics and projected spread and mutation of the virus

- In-silico comparative effectiveness studies to optimally power head-head studies with antibody/efficacy cartridges
- Virtual studies to rapidly optimize dose and minimize safety issues
- Rapidly power (adaptive) studies
- Detect any mutation of the H1N1 virus as it emerges.
- Project spread of disease and mutations

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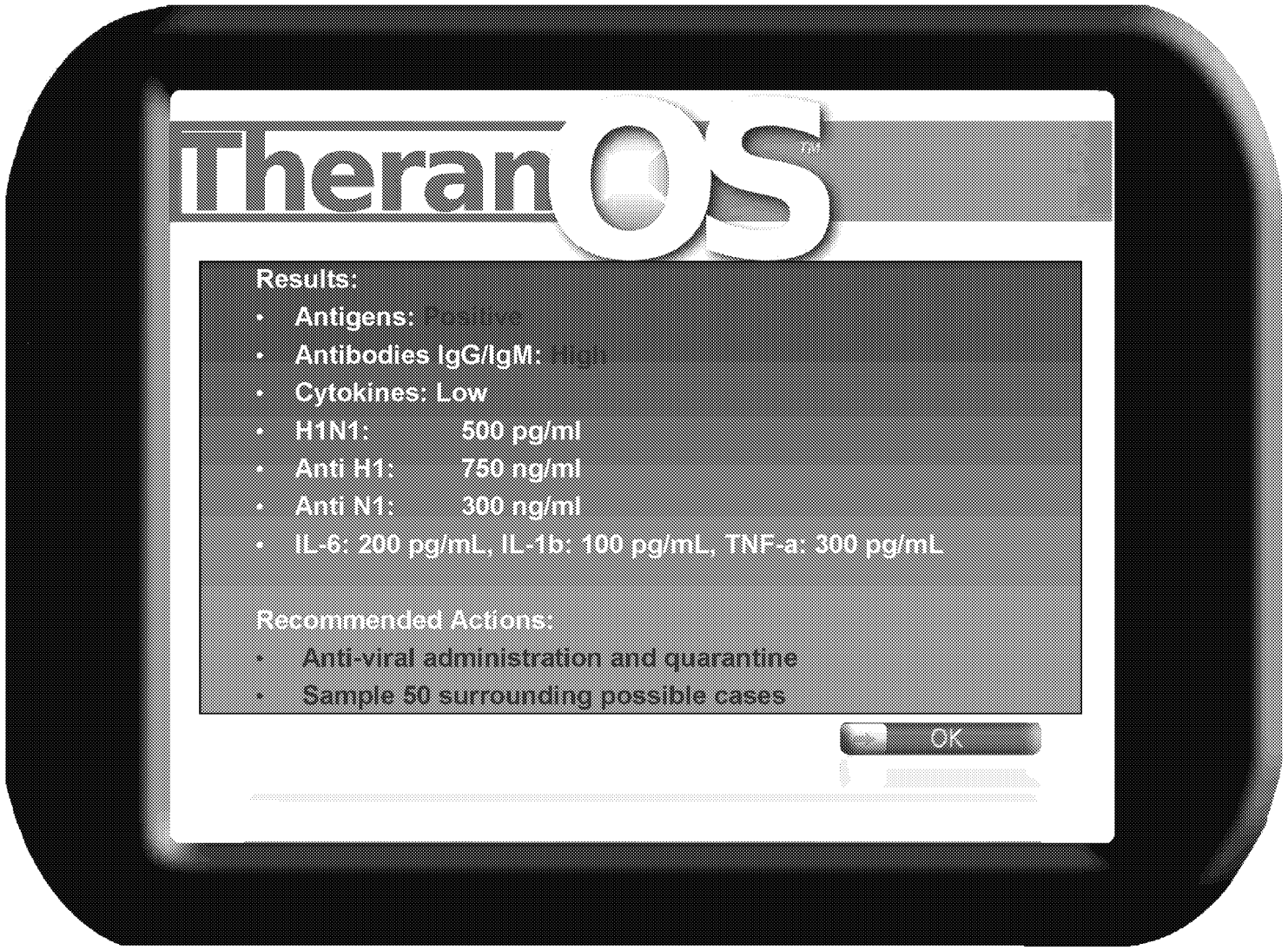

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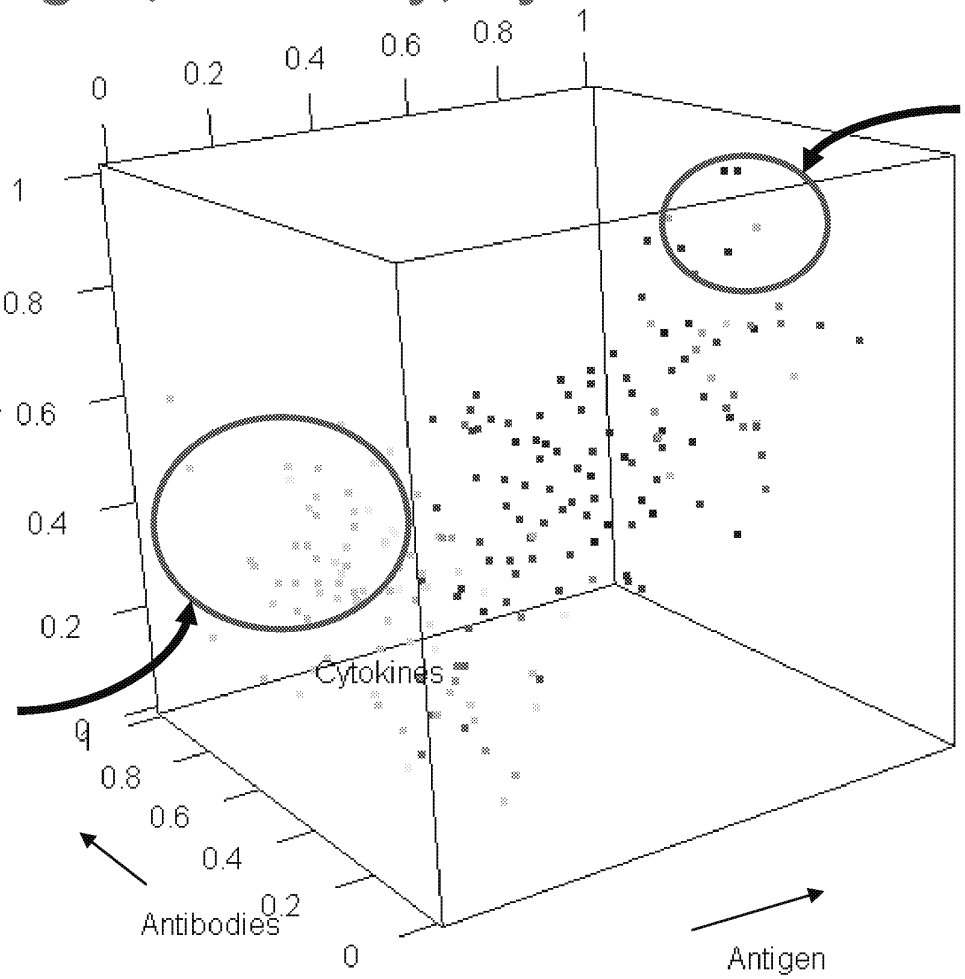
Recommended Actions Depend on Levels of Antigen, Antibody, Cytokine and Other Markers



Combination of high Ag, high cytokine, and low Ab suggests *hospitalizations*

Combination of low Ag, low cytokine, and high Ab suggests *prophylactic anti-viral administration and quarantine*

Colors classify patient "groups" for triaging optimal intervention

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THS Modeling Platform Capabilities

1. Predicts spread of an infectious pathogen in a heterogeneous human population.
2. Reflects the impact of regional demographics and patient risk factors.
3. Enables evaluation of healthcare mitigation policies, for example:
   - Surveillance/testing strategies
   - Hospitalization, home isolation, and quarantine policies
   - Prophylactic vaccination and anti-viral treatment policies
   - School and workplace closures; other social distancing measures
   Enables cost assessment and evaluation of quality adjusted life years (QALY) saved by comparing alternative mitigation approaches.
4. Is fully integrated with real-time data acquisition, enabling model updates based on the latest data acquired from multiple sources
5. Includes automated, frequent model updates.
   - Leads to more accurate projections for spread.
   - Allows health agencies to rapidly adapt to changing conditions.

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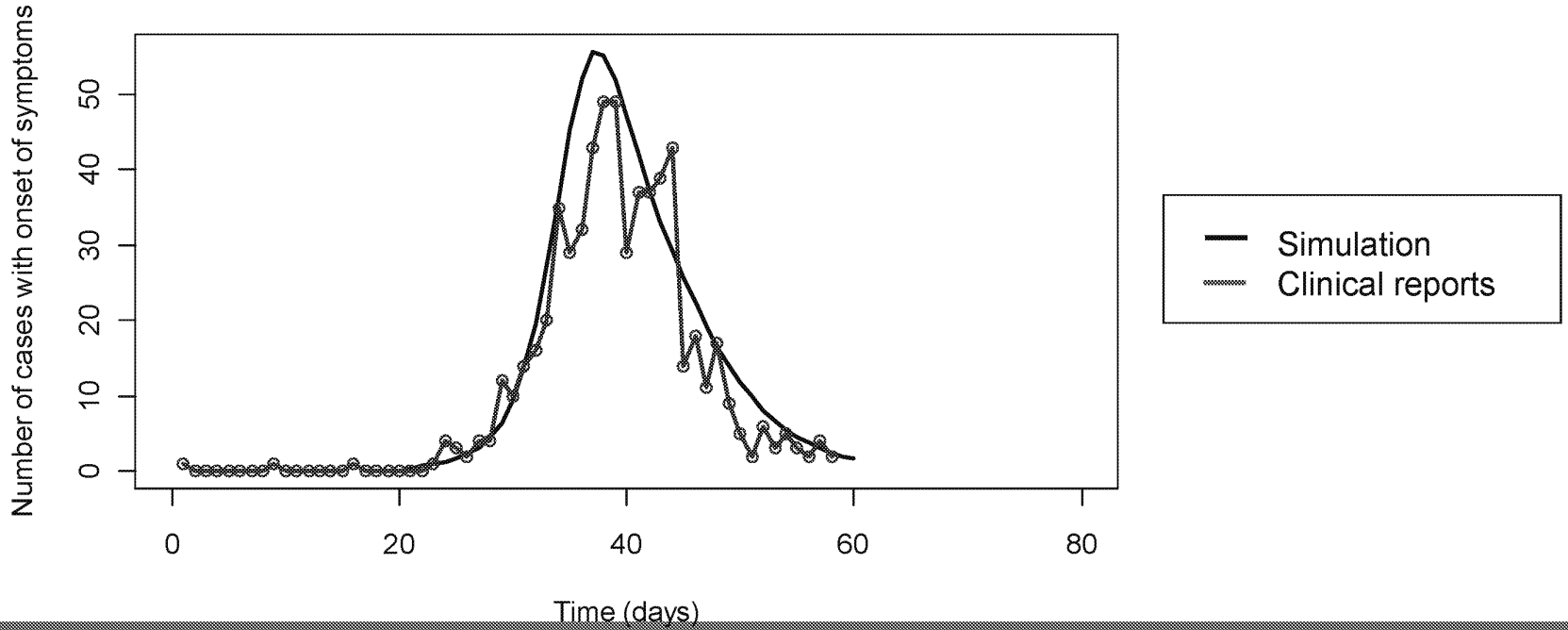
THS Model Accurately Reproduces Spread of La Gloria Outbreak

- All models are validated by reproducing historical data



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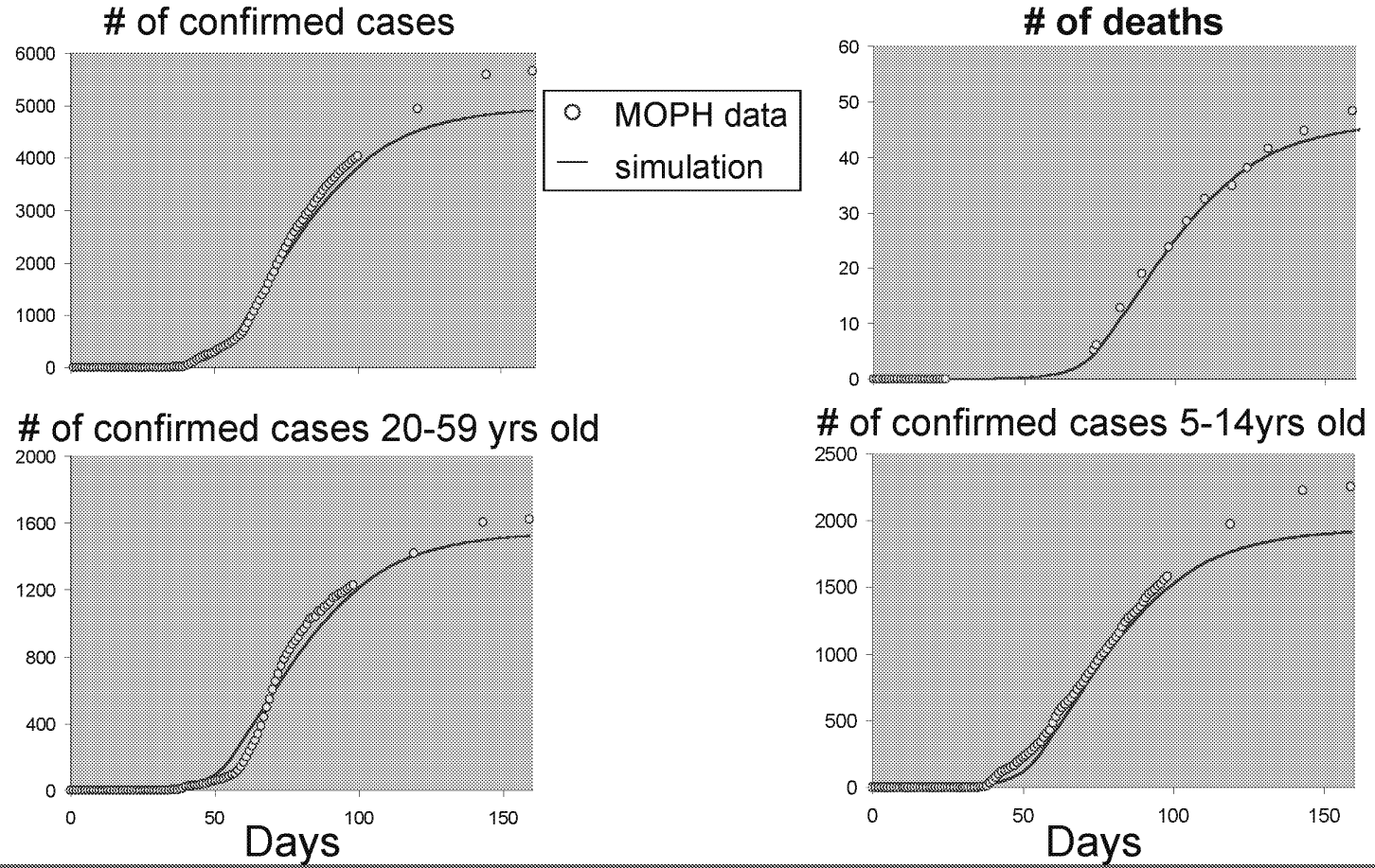
Model Reproduces Bangkok Publicly Reported H1N1 Data Including Deaths and Age-Dependence

Total cases ~20,000; reported cases significantly less.



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Selected Oncology Applications

- Rapid expansion of use through predictive visibility (models) and early reads (cartridges) on effiacacy and safety in new indications
  - MAGE-3 expansion
- Virtual and rapid head-head studies for comparative differentiation
  - Cervarix differentiation – characterization of velocity of antibody decay and need for re-boost
- Combination tests for low cost, real-time identification of antigen levels/presence of genetic signature from finger-stick of fresh whole blood run on point-of-care device in pharmacies, physician's offices, and other remote locations
  - MAGE-3 "responder" identification

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Deployment of GTS

- Decision support applications provide compounding predictive power
  - Inflammation/immunology/humeral response models form foundation of data analytics engine
  - Data analytics engine facilitates data integration and connectivity between disease-specific infrastructures:
    - Viral & Allergy Vaccines
    - Bacterial Vaccines
    - Emerging Diseases & HIV
    - Cancer Vaccines
- Data collection, analytics and surveillance infrastructure faciillitates Care Delivery in emerging countries through placement of devices in remote locations

Excerpts from GSK Metabolic Study Report

Nelson Rhodes, Director GSK Metabolic Biomarker Laboratory
Surekha Gangakhedkar, Theranos Assay Systems Lead

Background information:
The Theranos system was evaluated at GSK to profile active GLP-1 and C-peptide values and these data were compare to "gold standard" ELISAs using frozen human plasma from study XXXXXXX. The key project objectives (found in the attached statement of work) were:

- To assess the performance of the Theranos System in measuring a multiplex for GLP-1 and c-peptide values (the "Cartridge Analytes") as compares to the current gold standard ELISAs (which are not multiplexed).
    - Specifically, the study will assess Theranos' capabilities to detect points that the reference assays failed to accurately detect by running samples with C-peptide values in a standard range (ng/mL) and GLP-1 values between 0-3.2 pM
- To assess the functionality, specificity, reproducibility, accuracy, and precision of the Theranos System.
- Assess the Theranos data reporting and transfer functions

Thirty plasma samples (assayed in duplicate) were chosen based on historical GSK data for total GLP-1 levels from subjects given a mixed meal and two finger prick blood draws were performed. Five Theranos machines were used with active GLP-1 and C-peptide cartridges that required 20µL of plasma. MesoScale Discovery's (MSD) active and total GLP-1, Linco (Millipore) active GLP-1, and Linco (Millipore) C-peptide ELISAs were run as comparator assays.

GSK Metabolic Biomarker Lab comments:

- Data show good correlation
    - $r^2 = 0.90$ for GLP-1 (MSD vs. Theranos)
    - $r^2 = 0.96$ for C-peptide (Linco vs. Theranos)
- Inter-instrument precision (RLU average %CV = 11)
- Machines worked well
- Touch-screen interface was easy to use
- Cartridges were pretty straight forward (easy to handle and load)
- Assays took approximately 1 hour and 15 minutes per cartridge

Overall conclusions:
- The Theranos system eliminates the need for a lab and provided quality data
- The Metabolic Biomarker Lab has a favorable impression of the technology/system and recommends GSK clinical groups to work with Theranos

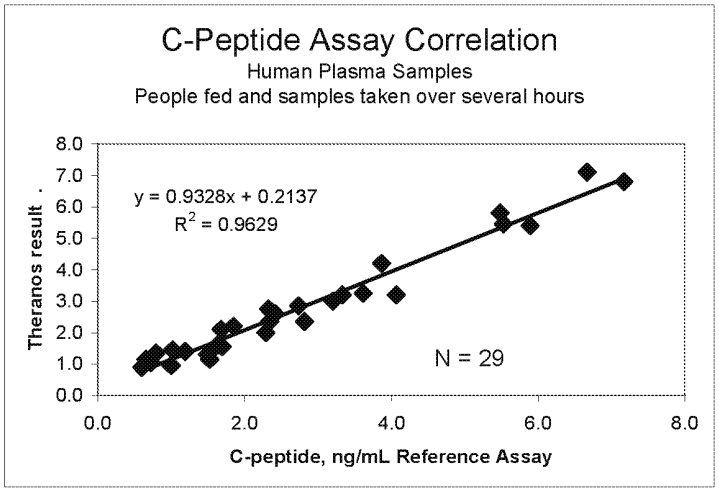
Data:

Study design

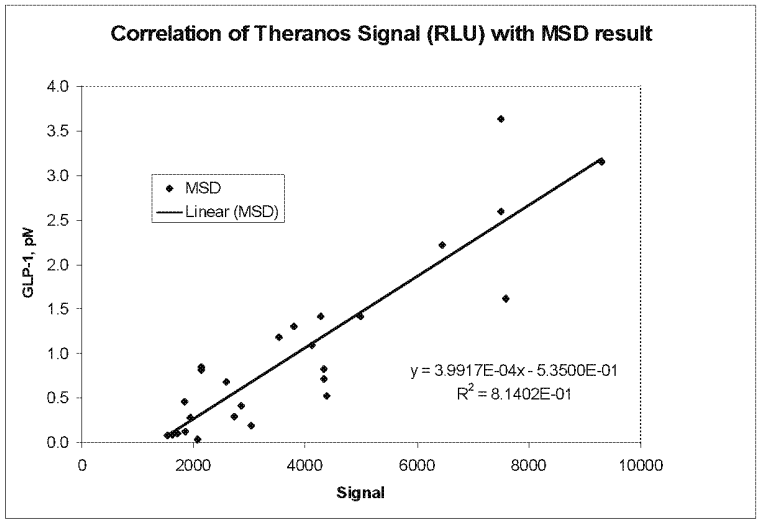
- Human subjects
- Food "challenge"
- Measure GLP-1 and C-Peptide multiplex over 5 time points
  - Linco Assay
  - MSD Assay
  - Theranos Assay

C-Peptide Assay

Averaged results



Calibration to GSK matrix



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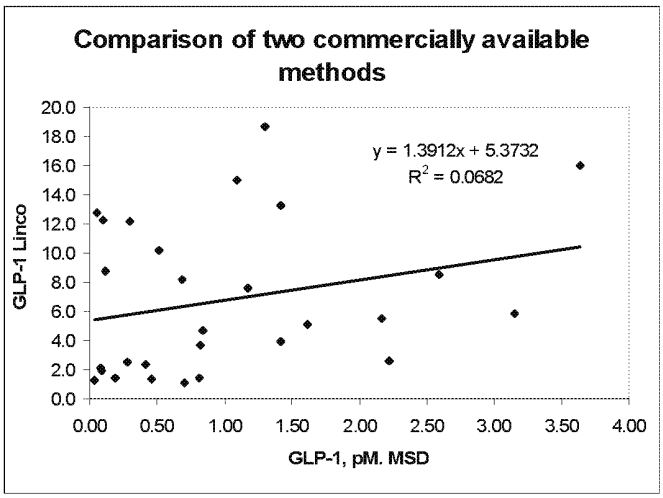
Lack of correlation of predicate methods



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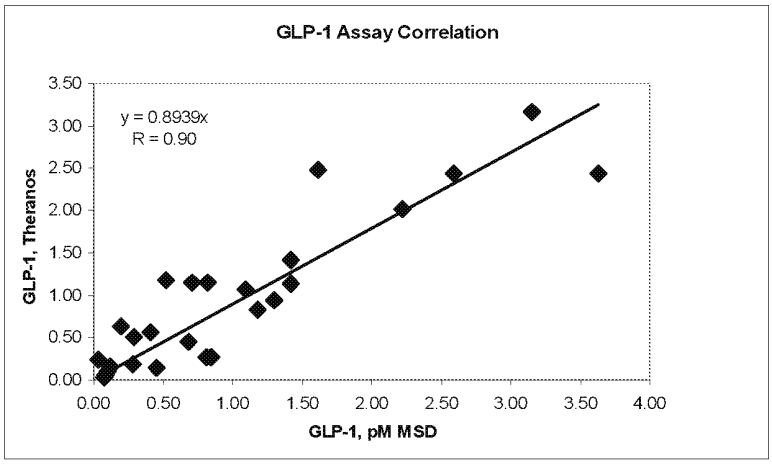
Assay correlation



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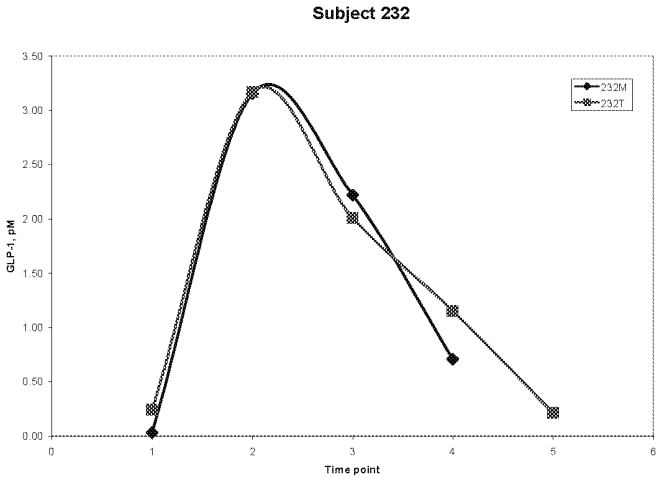
Subject 232



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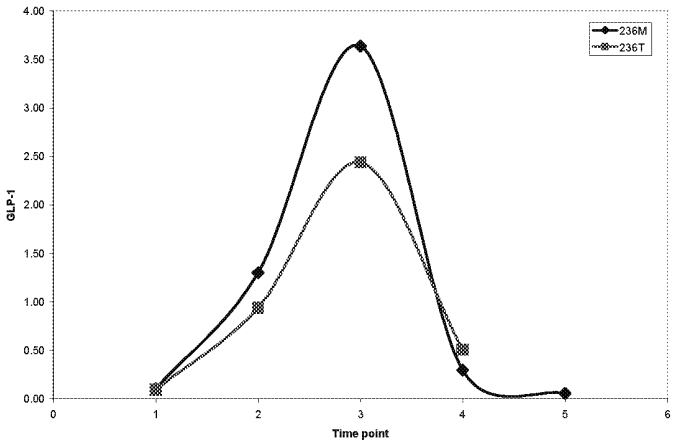
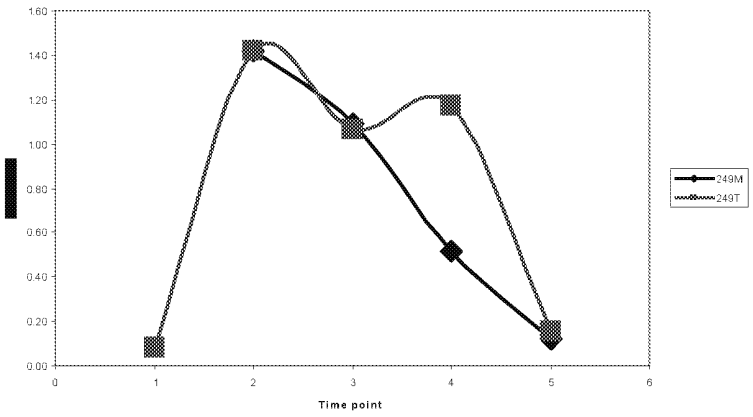
Subject 236



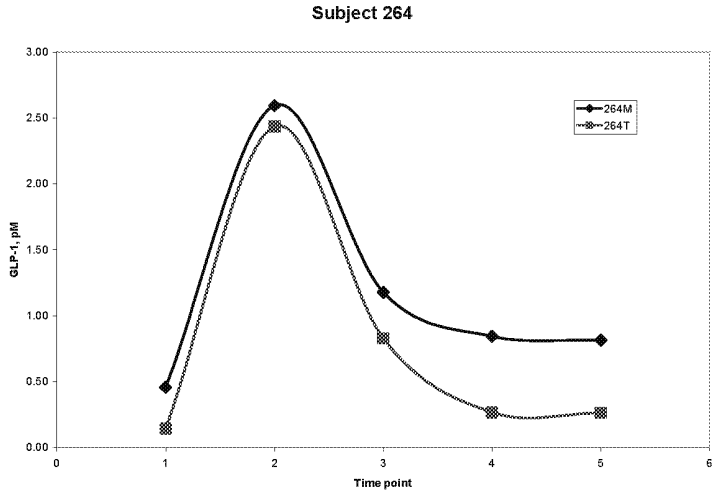
Theranos Confidential

Subject 249



Theranos Confidential

Subject 264



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Summary Statistics GLP-1 Comparison

- Theranos LOD = 0.17 pM
- Dynamic range measured: 0-3.2 pM
- Mean = 0.9 pM (Th), 1.0 (MSD)

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TPS Case Study: Client ROI

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Virtual Study Application

TheranOS Virtual Study Application enables more efficient clinical study design, conduct, and analysis through in-silico:

1. Comparison of alternative clinical study designs
2. Exploration of drug effects on multiple physiologic outputs
3. Examination of patient response variance in order to power the clinical study
4. Optimization of dose regimens
5. Examination of the magnitude and variance of side effects

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Virtual Study Application

TheranOS Virtual Study Application enables more efficient clinical study design, conduct, and analysis through in-silico:

6. Identification and selection of sub-populations having different physiologic responses
7. Identification of predictive patterns for early reads on efficacy and safety
8. Refinement of enrollment criteria.
9. Probability analysis of likely clinical outcomes for a given design.
10. Head-head studies for comparative effectiveness
11. …

Simulations can be run before a study is designed and dynamically throughout each study.

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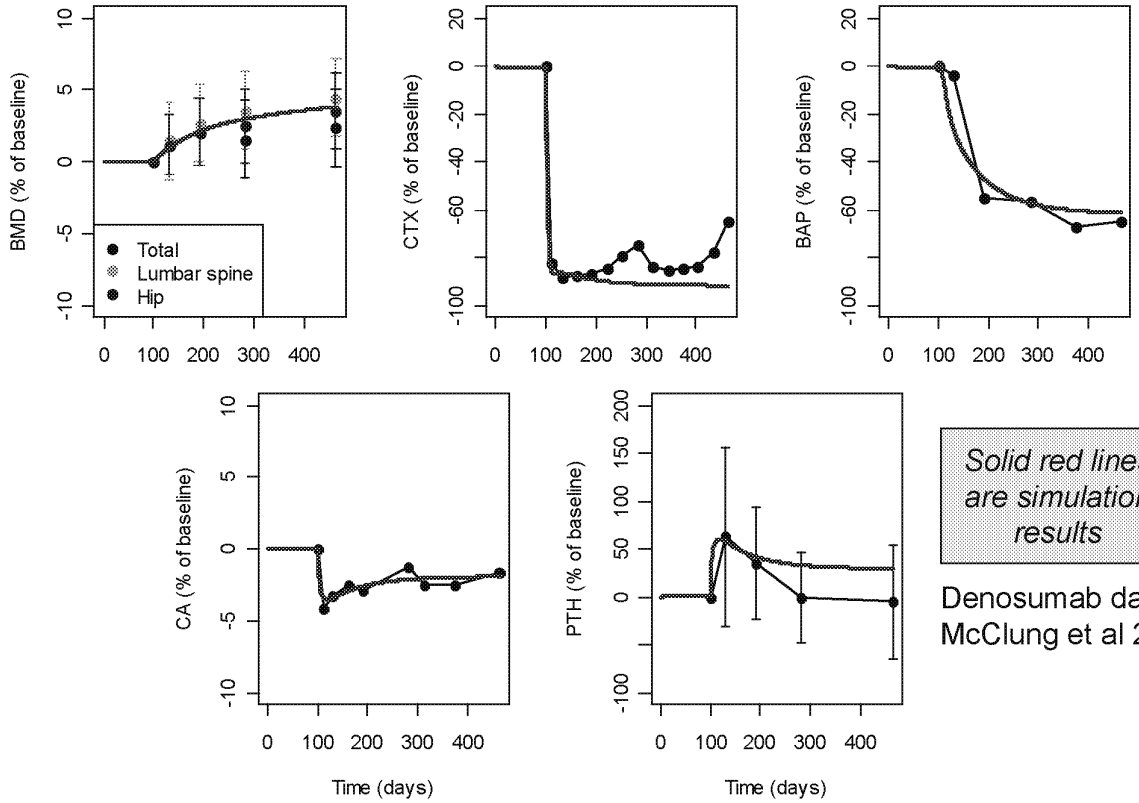
CASE STUDY M

TheranOS Comprehensive Physiological Models

Using the interconnected physiological modeling engine, simulated optimal therapy regimens for maximum efficacy and minimal adverse events for asset that acts on multiple pathways.

- 95% target inhibition reproduced key behaviors reported in the clinical study of compound
- The model predicts the efficacy profiles of the drug, even without accounting for its *mechanism of action* (MOA models built for other drugs)
- Model identified a predictive signature of BMD that is measurable ~6 months prior to physical changes in BMD
- www.theranos.com



Solid red lines are simulation results

Denosumab data: McClung et al 2006

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CASE STUDY B

Example of TPS in Compound Development for Anemia and Bone-related Disease

1. Customized TheranOS for automated data integration, analysis and real-time self-learning
   - Compounding predictive power from all Client-generated data
2. Developed and validated physiologic-based mechanistic modeling and simulation system
   - Captured effects of target inhibition by Compound treatment
   - Included target patient phenotypes based on literature and healthy patient responses to Compound
   - Optimized design, evaluation, execution of (adaptive) clinical trials for Compound
   - Led to novel biomarkers for efficacy and/or safety, enhancing patient treatment with Compound

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CASE STUDY B

Example (cont'd)

3. Virtual Study Application used to optimize Phase IIa trial design for target patient population
   - Recommended designs enhance power of trial
     - Increased probability of success
     - Provided support for regulatory reviews
   - Integrated data sets and models used by Client to run in-house simulations
   - Easy-to-use interface for in-house ownership/use of highly complex, proprietary modeling system
4. TheranOS applications integrated with Theranos Field Systems yielding compounding predictive power
   - Automated data integration, analysis, self learning and model refinement for trial design, analysis, and patient monitoring
   - Extended to include additional indications for Compound and for other compounds and their indications/target profiles

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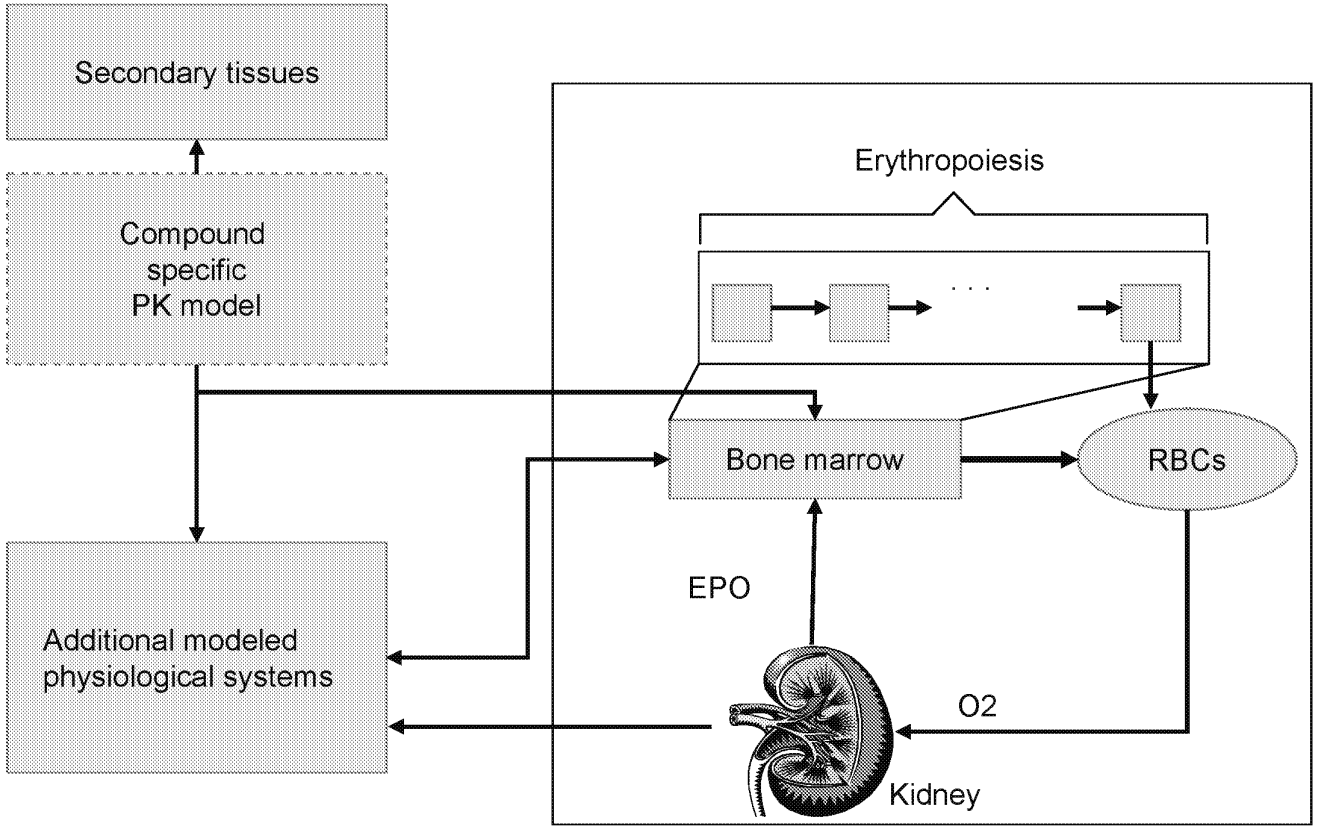
CASE STUDY B

Schematic Overview of Physiological Model



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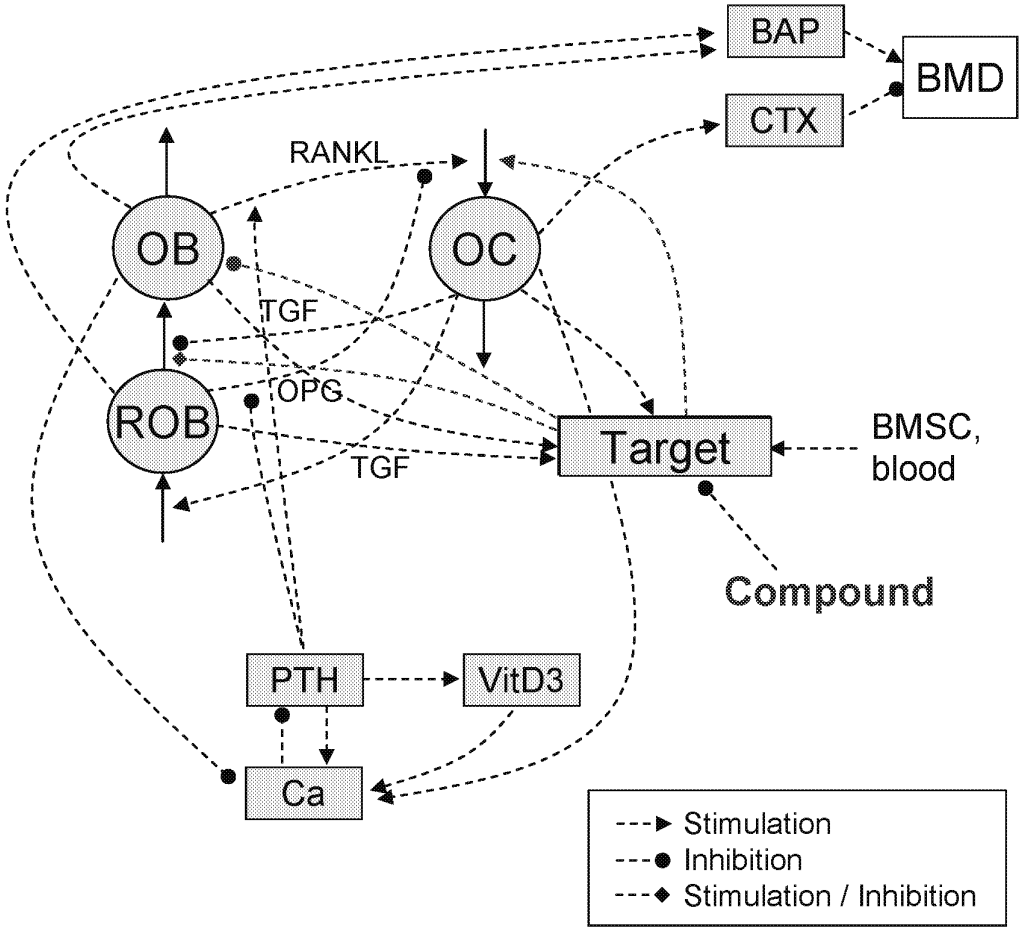
CASE STUDY B

Summary Illustration of Quantitative Model Representing the Dynamics of Bone Metabolism



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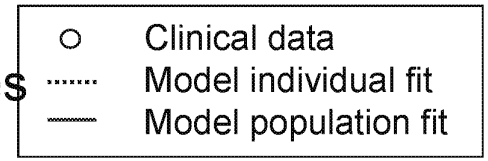
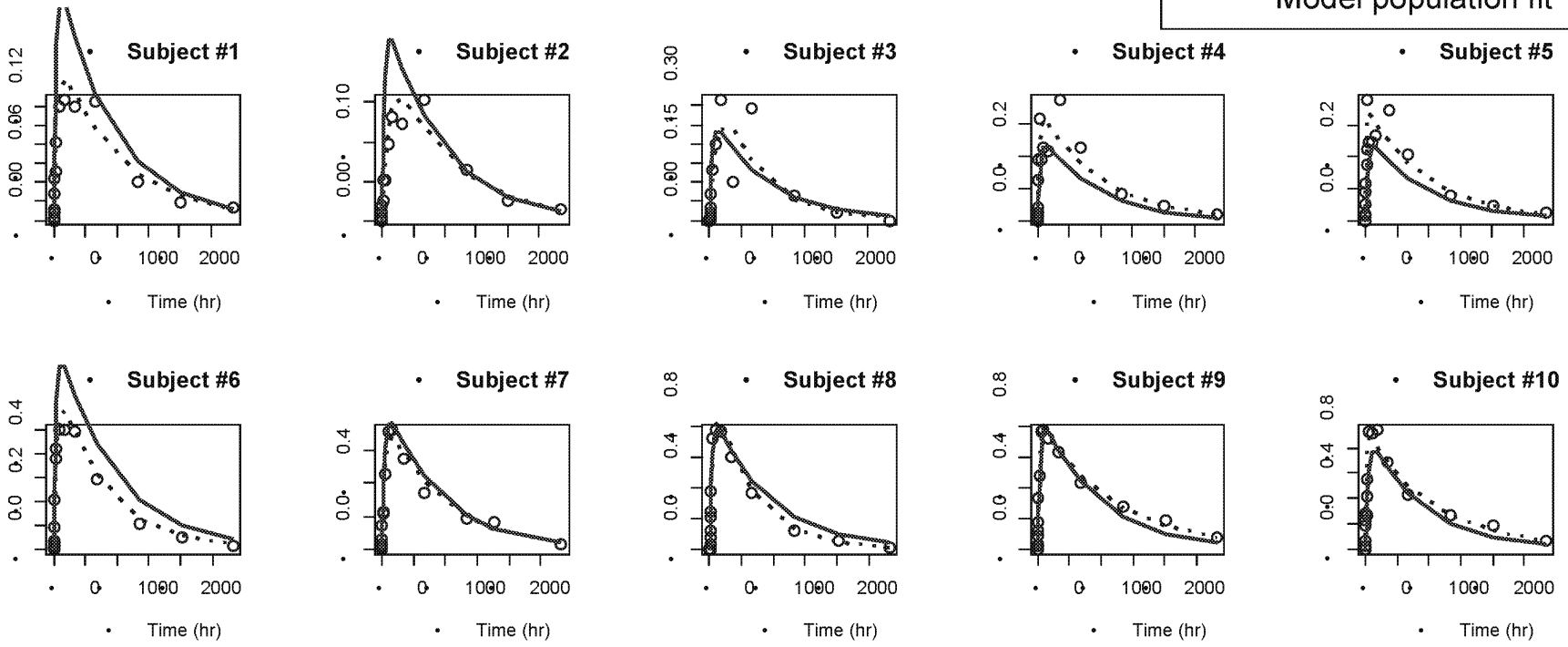
CASE STUDY B

Pop-PK Mixed-Effects Modeling for Compound SC Administration

- First-order one-compartment model was used to fit the Compound SC PK data.
- Model data accurately predicts clinical PK profiles





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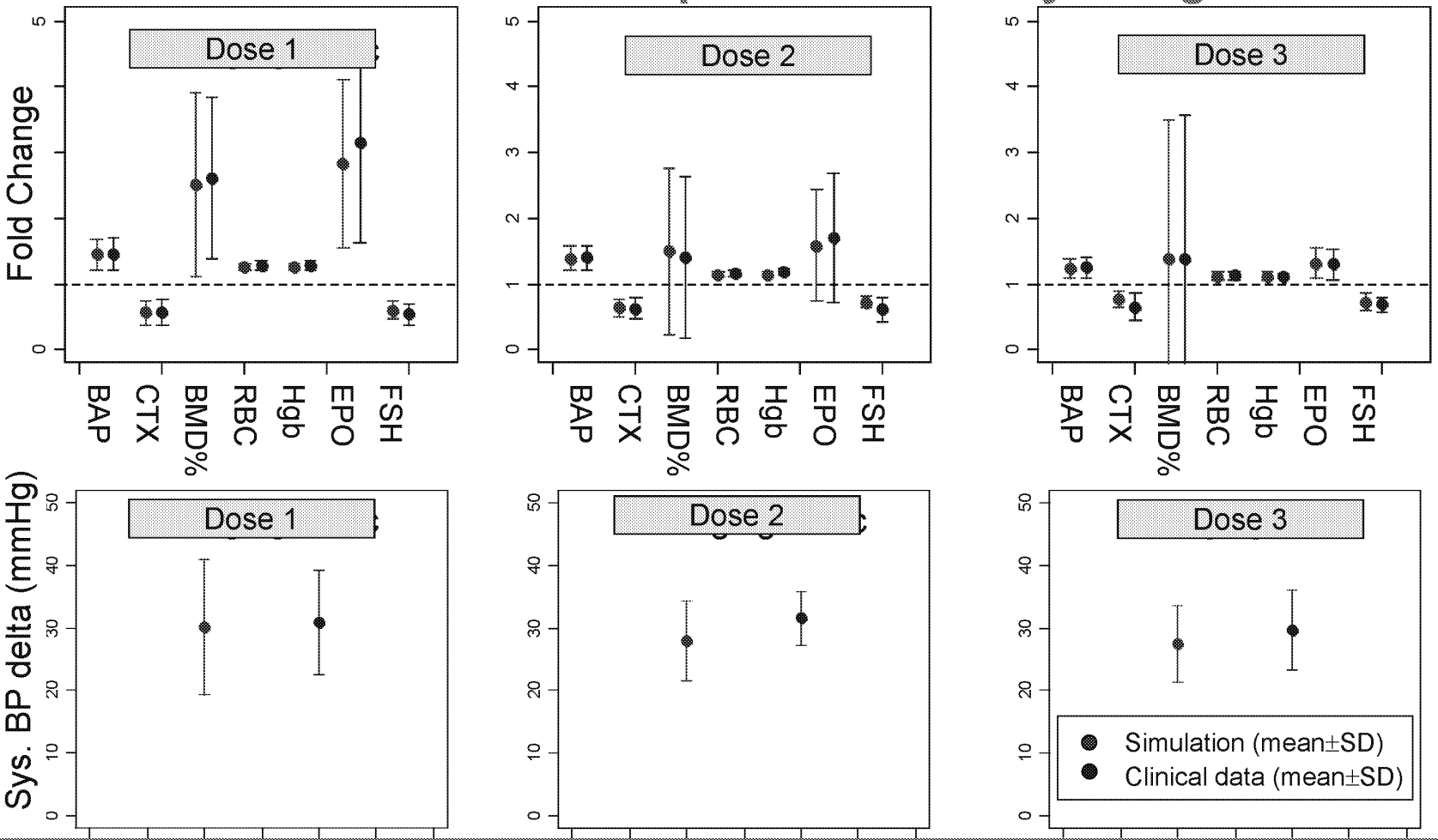
CASE STUDY B

Simulated Peak Responses Predicted High, Mid, and Low Dose Response for All Physiologies



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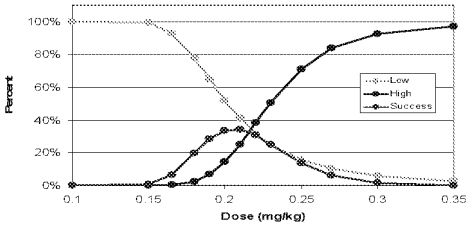
CASE STUDY B

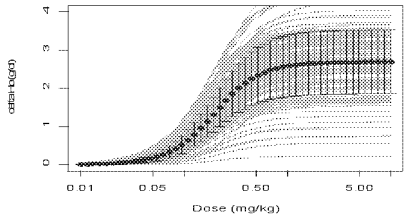
Virtual Study Application Increased Study POS

Simulations increased probability of study success by allowing users to optimize protocol and dosing titration schemes in-house prior to study initiation.

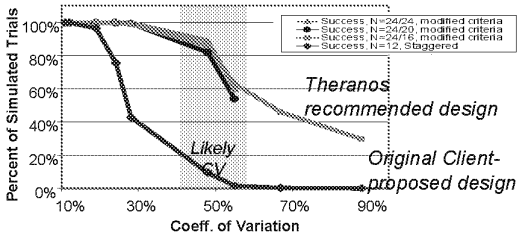
Simulation of probability of 'successful outcome' indicated high probability of study failure …



… due to underlying variability of responses



TPS optimized study design, dosing regimen, and titration parameters, increasing the probability of success 5x



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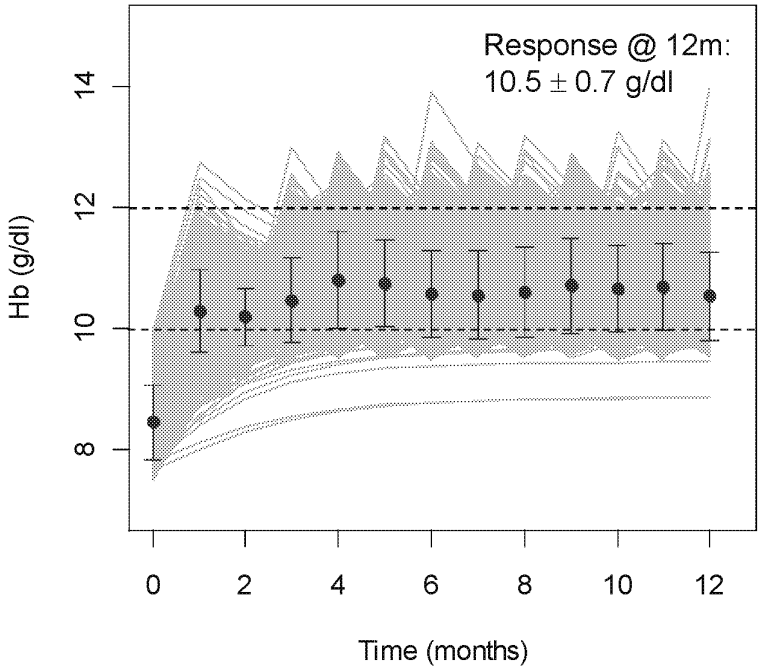
CASE STUDY B

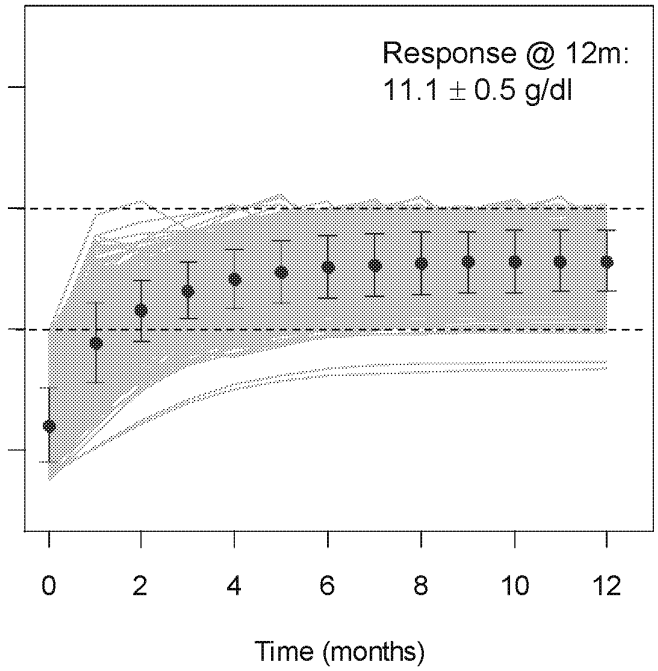
Virtual Study Application used to improve POS

New titration design resulted in lower variance, leading to fewer excursions above maximum desired response and significantly decreasing frequency of safety issues.

Initial Client Titration Design (A)



The Theranos Solution Modified Titration Design (B)



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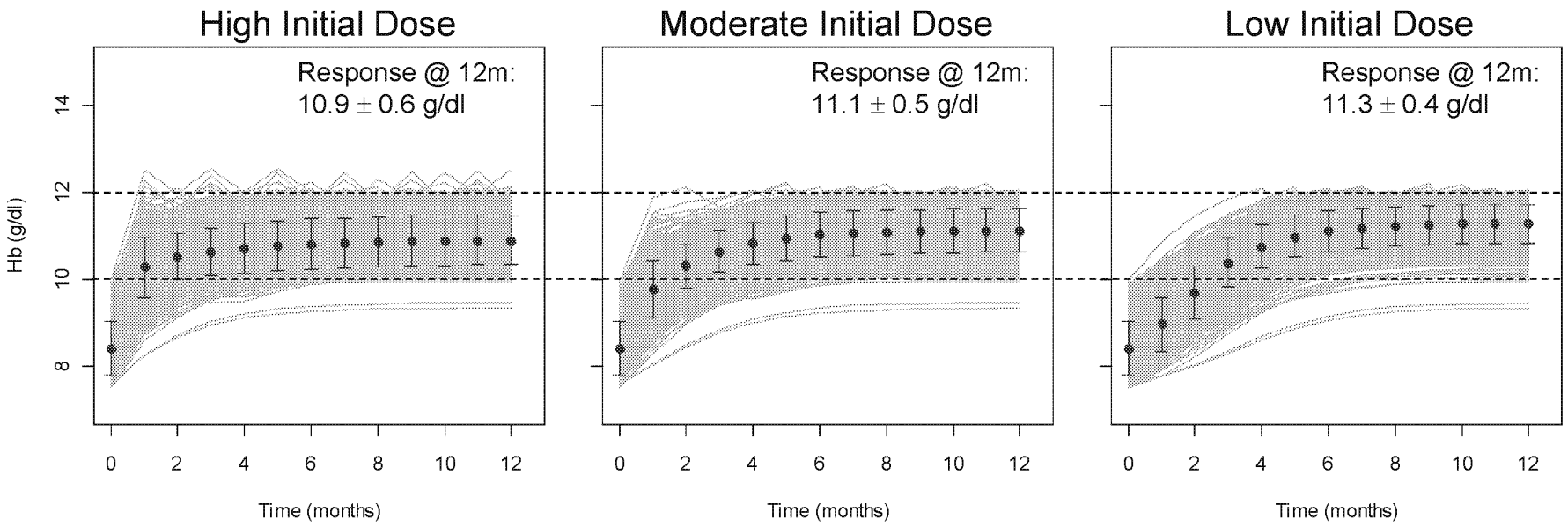
CASE STUDY B

Further Dose Titration Optimization

Further optimization of dose titration yielded even better efficacy and safety across three initial dose scenarios.



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Safety and Efficacy Profile

Based on this safety and efficacy profile, the final design was recommended, as it:

- Significantly enhances both safety and efficacy under all conditions for heterogeneous patient populations
- Improves long-term Hgb maintenance by reducing “on-off” dosing and wide Hgb swings
- Reduces variance of Hgb response and treatment dose
- Is robust to initial dose given to the cohort

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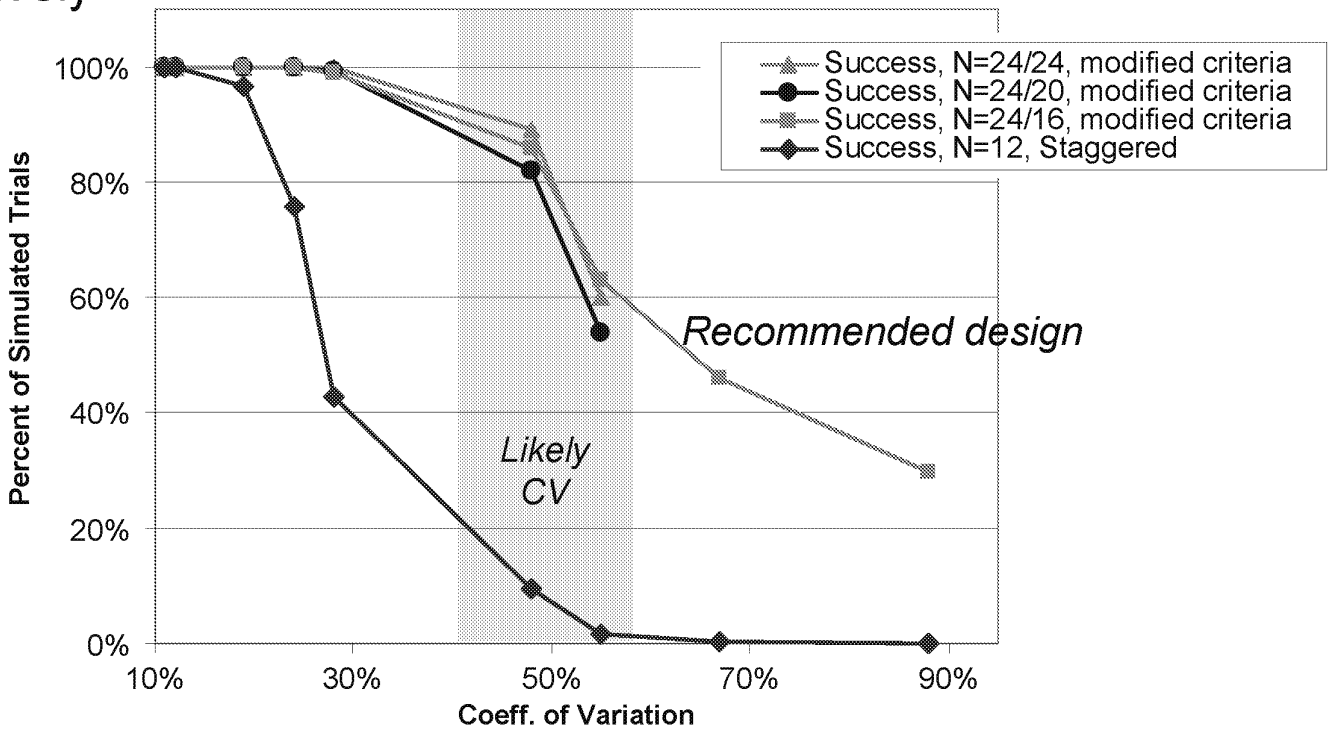
CASE STUDY B

Proposed Semi-Parallel Trial Design is Estimated to Increase the Probability of Success from ~15% to ~80%

Recommendation: semi-parallel design has good chance of success for n=24 and n=16 in initial cohort and parallel cohorts, respectively



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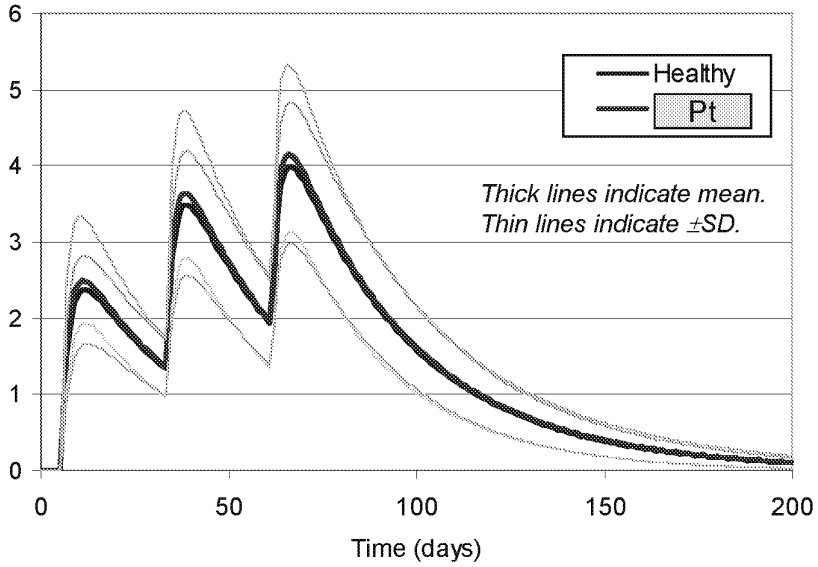
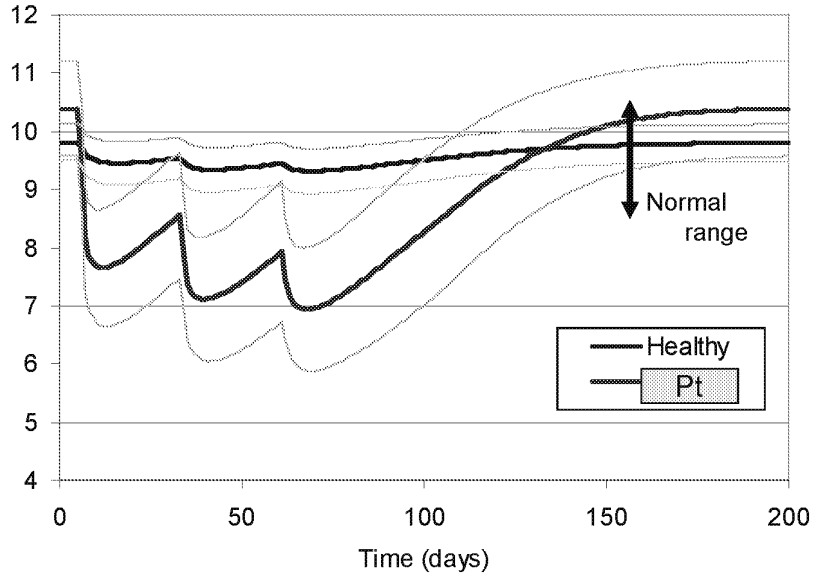
CASE STUDY B

Model Illuminates Secondary Safety Concerns

Model indicates that Compound treatment may lead to secondary safety concerns in target patients undergoing treatment, if not taken into account.





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CASE STUDY B

Secondary Safety Concerns

Model indicated that Compound treatment may lead to secondary safety concerns in target patients undergoing treatment

1. Severe hypocalcemia after intravenous administration of bisphosphonates has been observed in patients with poor mineral regulation.
2. Target patients present a particular risk due to limited endogenous mineral regulation.
3. Phase I studies with Compound in healthy patients show limited Ca effects due to normal mineral regulation in these patients.

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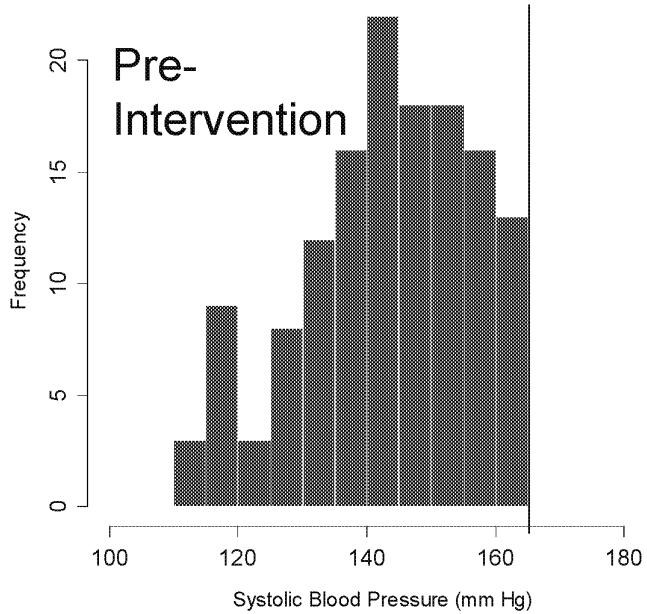
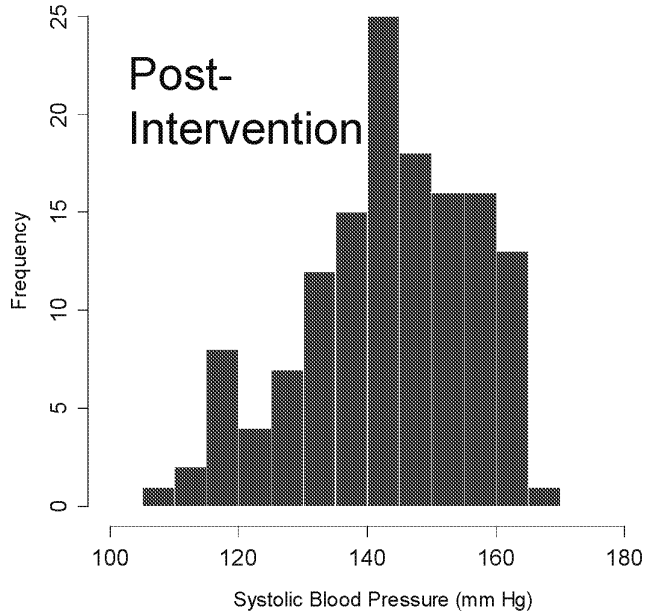
CASE STUDY B

Enhanced TheranOS Patient Cohort

After safety review, shows excellent agreement with Client data on variability in pre- and post- BP of patients.





Population mean: 150.6 mmHg
Population SD: 18.0 mmHg

143.2 mmHg
13.3 mmHg
} [Rohrscheib et al, CJASN , 2008]

Population mean: 149.3 mmHg

141.0 mmHg
} Data from Client, Oct 27 2009

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CASE STUDY B

Summary of Dose Titration Optimization for Hgb Maintenance and BP-Related Safety Profile

		Dose titration designs			
	Endpoints	**B3**	**B3a**	**B4**	**B5**
All Patients	Safety profile (% population with high BP events)	**8**	**17**	**8**	**10**
	Hgb response at 1 month after last dose, (% responder patients within target Hgb range, 10-12 g/dL)	**62**	**91**	**78**	**86**
Excluding patients with baseline BP>160 mmHg	Safety profile in absence of high baseline BP patients >160 mmHg, (% population with high BP events)	**0.8**	**6**	**0.8**	**1.6**
	Hgb response at 1 month after last dose, (% responder patients within target Hgb range, 10-12 g/dL)	**67**	**91**	**82**	**90**
Implementation logistics	Information required for calculating each dose	• ΔHb since last dose • ΔHb since 1st dose • Current Hb		Additional Info • Baseline BP	Additional Info • Current BP • Max ΔBP since last dose • Max sys BP since start of trial

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CASE STUDY B

Summary of Trial Design Results and Insights Based on Modeling and Simulation

Using TheranOS model, optimized dose titration and Phase II clinical designs for target patients to meet clinical objectives, improve success probability, and accelerate development timelines

- Dose titration design predicted to improve efficacy across cohort of heterogeneous patients with improved safety profile (limits large/rapid Hgb excursion)
- Evaluated and proposed initial starting Compound dose for target patients to enhance response magnitude and rate with suitable safety profile
- Proposed semi-parallel trial design and modified success criteria predicted to increase statistical power from 15% to 80%

Selected insights based on model development included:

- Rapid hypertensive response may be due to three contributing factors: direct pharmacological effect, rise in viscosity (RBC), delayed rise in EPO (vasoconstriction).
- Identification of candidate biomarker (CTX/BAP ratio) for the prediction of BMD % change
- Delayed transient increase in EPO may be indicative of abnormal RBC/Hgb function.
- Compound treatment predicted to lead to secondary safety marker in target patients.

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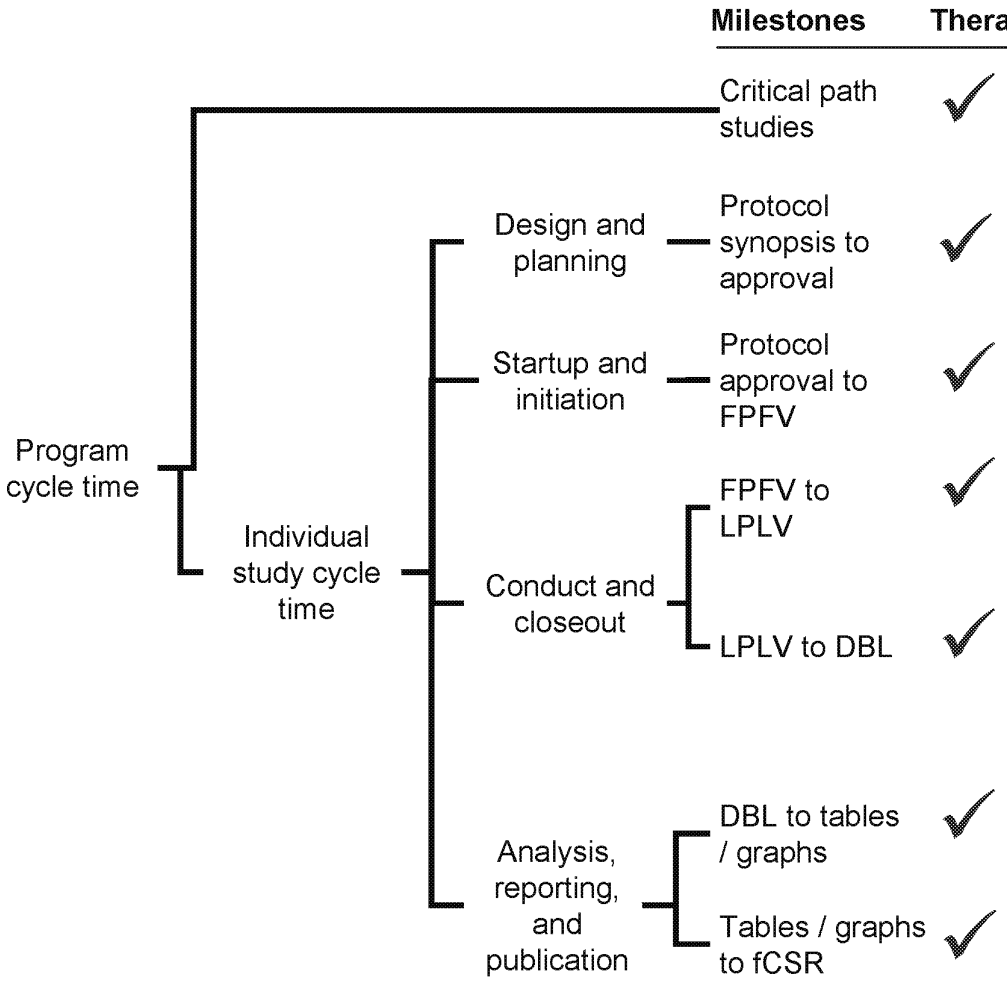
ROI: Accelerating Timelines and Improving POS



- Data Quality significantly improved through integrated data linkage and earlier & better visibility into exposure-response and patient-patient visibility
- Advanced modeling and simulation capabilities reduced need to run certain trials (e.g., add'l PK/PD studies)
- Optimized trial design and dose selection reduces possibility of re-running trials
- Use in remote locations (e.g., off-shore) significantly impacts site performance
- Real-time, Adaptive Decision Support improves POS
- 15uL blood sample enables far more frequent sampling than historically possible, yielding higher integrity data, faster
- Reduces need for central lab sample shipping / analysis
- Reduces need for clinic visits
- Decentralized and automated nature of sample collection reduces number of sites / investigators Standardized real-time linkage
- Eliminates CRO and in-clinic overhead (and costs)
- Real-time data linkage reduces overhead associated with data handling / storage
- Reduced number of queries
- TPS real-time linkage impacts DBL to analysis by reducing need to consolidate various datasets

Note FPFV: First patient first visit; LPLV: Last patient last visit; DBL: Database lock
SOURCE: CMR; interviews; McKinsey analysis

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CASE STUDY B

Client ROI from POS Analyses & Recommendations

- Overview
  - Client with PoC study design question
  - Compound being used in anemia
- The Theranos Solution utilization
  - Theranos builds systems model to simulate PoC studies
  - Theranos recommends new PoC study design
- The Theranos Solution impact
  - Theranos increased probability of success from ~15% to ~80%
  - Theranos study design eNPV impact of ~$202 million

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CASE STUDY B

The Theranos Solution – Overview

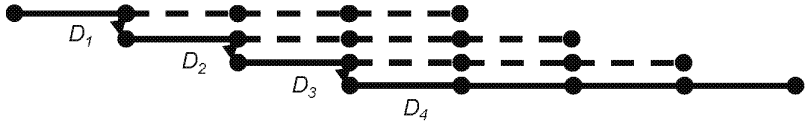
Build predictive model and use it to design proof-of-concept study.

Overview

- Theranos asked to build a predictive model for a drug with highly complex interacting physiologies and tightly limiting safety concern
- Theranos used the model to help design a proof-of-concept study that improved odds of success

Client design

- Client had originally designed a proof of concept study that included
  - Staggered dosing regimen



  - Titration regimen that had high degree of variability in patient responses (bouncing between too strong or too weak a response)

- Client had indicated that if the compound failed in the PoC study, there were 3 likely outcomes
  - Terminating compound development
  - Re-doing PoC study
  - Taking forward multiple doses forward for Phase 2b

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The Theranos Solution – Utilization

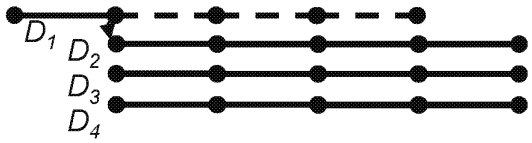
Built complex model and proposed optimized study design within 6 months.

Timeline of events

- Feb, Theranos receives request
- Mar, Theranos receives data to begin modeling
- Jun, Complex systems model built from scratch, with initial physiologically meaningful results
- July, Systems model and simulations completed with solution delivered to Client

Theranos Solution

- The Theranos Solution improved odds of success in a number of ways, including:
  - Building a complex systems model
  - Proposing a new proof of concept study design based on extensive simulation of underlying physiology including
  - Proposing a semi-parallel dosing regimen



  - Proposing a new titration regimen that reduced the likelihood of excursions above the maximum desired response and reduced the number of low-responders

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CASE STUDY B

The Theranos Solution – Impact on Success

Optimized study design increased probability of success from ~15% to ~80%.

Theranos Impact

- Probability of success through study design
  - New study design optimized dosing and titration regimens to patient responses, resulting in improved odds of success from ~15% to ~80% by causing:
    - Fewer excursions above highest dose range
    - Faster average onset of action
- Guidance to regulatory agency
  - Theranos accompanied client at meetings with regulatory agency to present new study design and rationale (and then designs for all following studies)
- Client reaction
  - Client believes The Theranos Solution study design significantly reduced likelihood of (re-)running additional studies; Estimates an impact of 18+ months saved in clinical development timeline

- ***Theranos improved Quality*** *by i*mproving probability of success through optimized study design with eNPV impact of $202 million (see next slide)
- ***Theranos also improved Speed/Cost*** *by reducing the need to* re-do PoC study (typical PoC 18-24 months, $10-$20 million)

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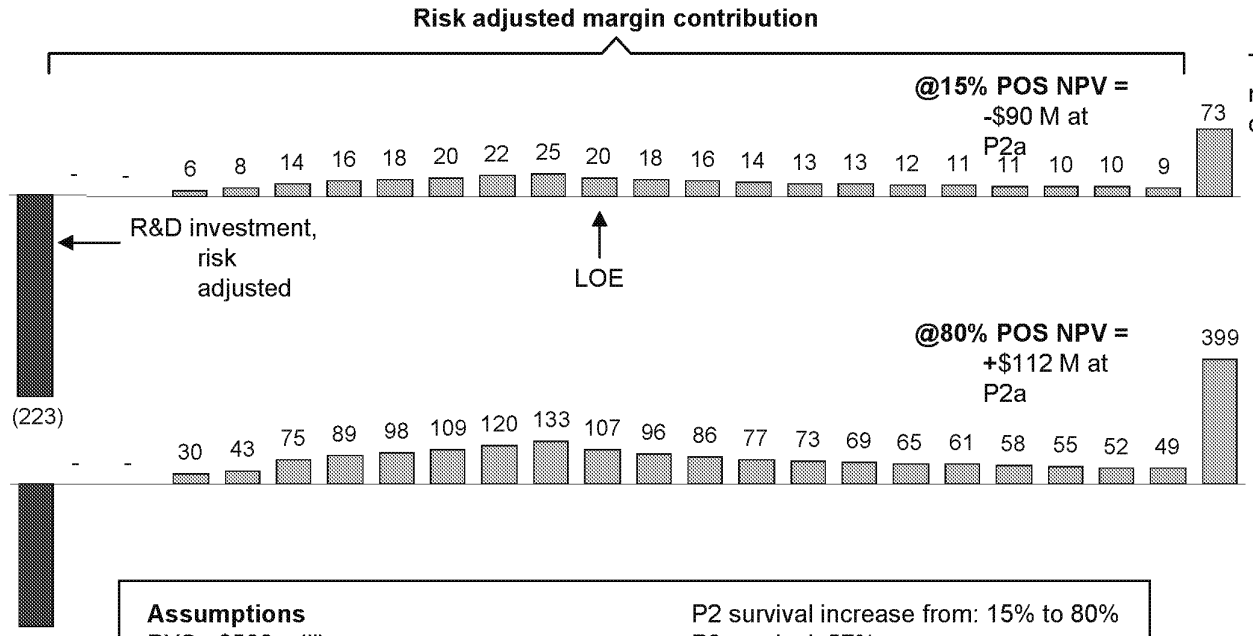
CASE STUDY B

Improving probability of survival in PoC from 15% to 80% resulted in eNPV of ~$202 million for late market drug entrant



Assumptions

PYS: $500 millions	P2 survival increase from: 15% to 80%
WACC: 8%	P3 survival: 57%
Contribution margin: 0%, 50%, 70%, 60%	Reg survival: 84%
R&D capitalization rate: 9.5%	P2 cycle time: 3.1 yrs
Revenue profile: Biologic	P3 cycle time: 2.8 yrs
	Reg cycle time: 1 yr

- Discounting cash flows to beginning of P2 results in expected **NPV difference of ~$202 million** by increasing probability of success
- Return on R&D investment for successful launched compound with the profile indicated would have **increased from -3.6% to +13% (an increase in return of ~10 percentage points)**

SOURCE: PharmaProjects; DiMasi et al. 2002 Journal of Health Economics

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CASE STUDY B

The Theranos Solution – Impact on ROI

Assumptions:

- Late-to-market drug
- Potential safety issues
- Competing against established drugs
- Minimal peak year sales and success probabilities

Initial Probability of Success of 15%

- At Phase 2, value of the drug is -$90 million
- Economically unfeasible at proposed success rate
- Development is likely to be stopped
- Considering development investment to date, IRR = 3.6%

Theranos Improvement to Probability of Success of 80%

- At Phase 2, value of the drug became +$112 million
- Theranos added ~$202 million value
- Theranos effectively increases ROI to 13%.

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CASE STUDY B

Eliminating the need to repeat a single study accelerated development (estimated 18-24 months)

TPS impact

- Return on R&D investment for successful launched compound **increased ~10 percentage points**
  - Further reduction of fully loaded cost of R&D and increase of revenues from time savings
- By realizing the improvement in attrition rate across the entire portfolio versus just one compound, biopharmaceutical companies are realizing a further reduction in the fully loaded cost of R&D, because in an aggregate portfolio fewer wasted trials yield lower spend for the overall portfolio irrespective of development timelines.

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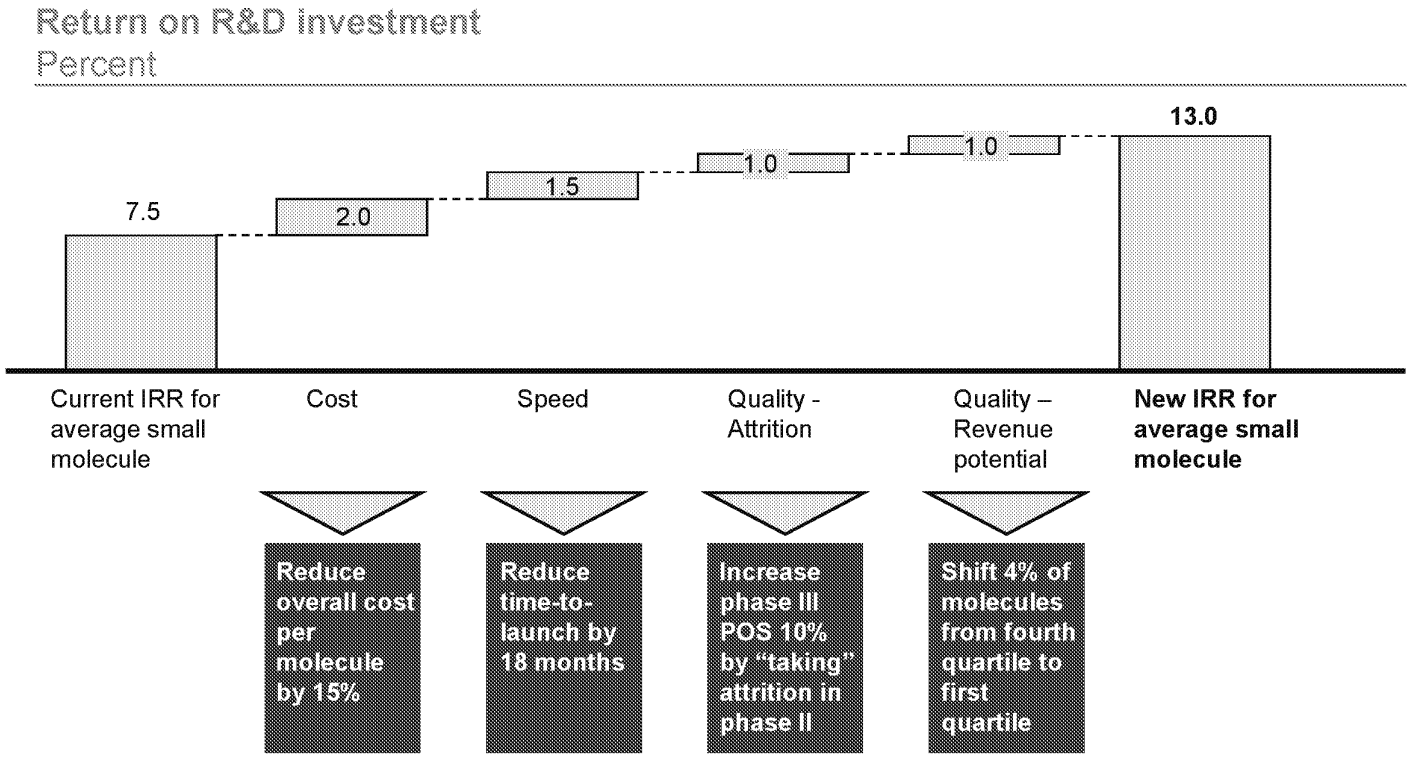
Increasing Return on R&D Investment

External research shows that pulling several operational levers can increase return on R&D investment.



SOURCE: E. David, et al. "Pharmaceutical R&D: The Road to positive R&D returns", ***Nature Reviews Drug Discovery***

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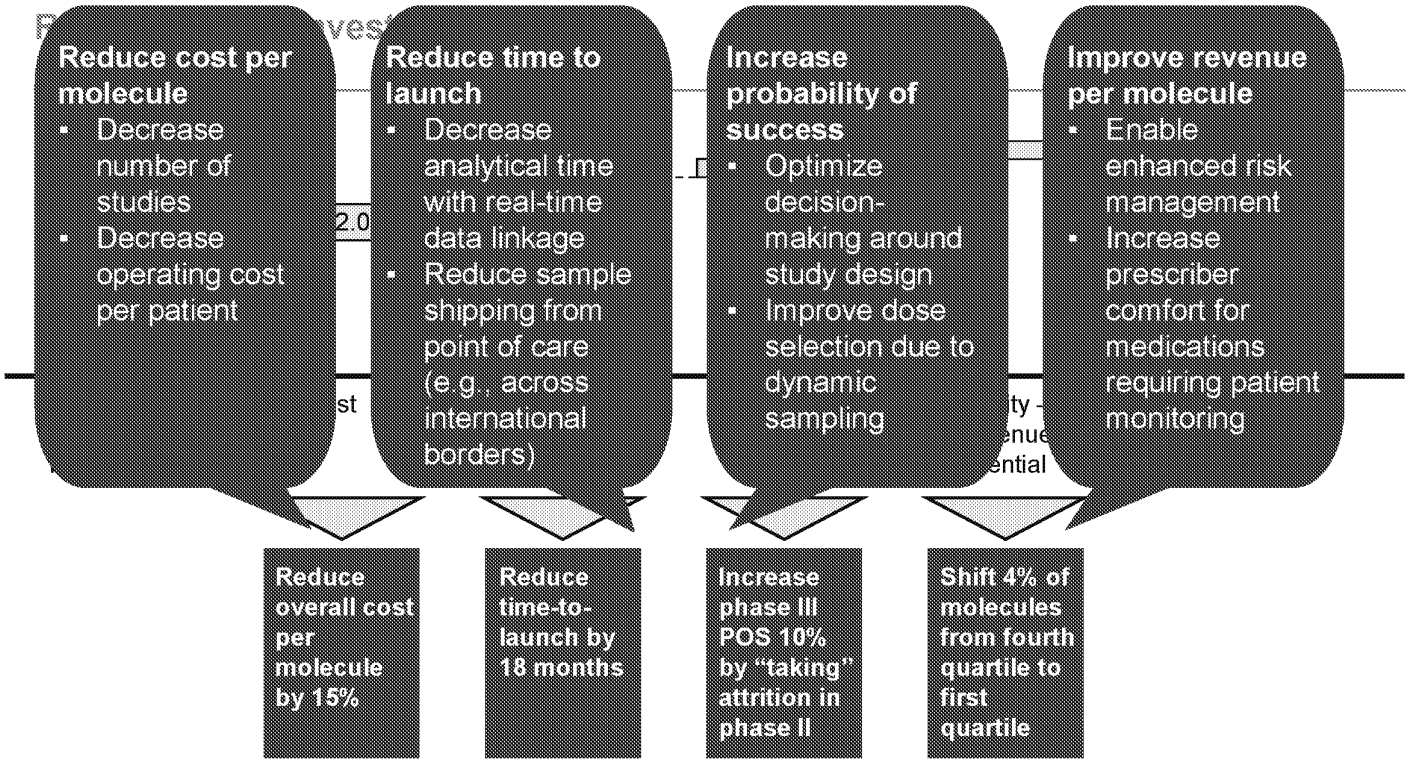
Theranos can help achieve these improvements.



SOURCE: E. David, et al. "Pharmaceutical R&D: The Road to positive R&D returns", ***Nature Reviews Drug Discovery***

Exhibit 8

To: Bruce Shepard[Bruce.Shepard@wal-mart.com]
Cc: Sunny Balwani[sbalwani@theranos.com]
From: Elizabeth Holmes
Sent: Fri 3/19/2010 7:45:58 PM
Importance: Normal
Subject: RE: times to talk
Received: Fri 3/19/2010 7:46:00 PM
Multiplexed Panel Validation Report_FDA-ICH.pdf

Bruce,

Great to talk with you. Please find the FDA/ICH validation report we discussed attached to this email. We'll follow up with you on the store location recommendations and biohazard guidance under separate cover.

All my best,

Elizabeth.

From: Bruce Shepard [mailto:Bruce.Shepard@wal-mart.com]
Sent: Wednesday, March 17, 2010 12:50 PM
To: Elizabeth Holmes
Subject: RE: times to talk

Just sent the meeting planner. Thanks Elizabeth!

Thanks,
Bruce Shepard
479.204.6857
bruce.shepard@wal-mart.com

From: Elizabeth Holmes [mailto:eholmes@theranos.com]
Sent: Wednesday, March 17, 2010 2:47 PM
To: Bruce Shepard
Cc: Sunny Balwani; Carolyn Balkenhol
Subject: RE: times to talk

Bruce.

Let's do it Friday. We can call your office at 10 AM CST?

Elizabeth.

From: Bruce Shepard [mailto:Bruce.Shepard@wal-mart.com]
Sent: Wednesday, March 17, 2010 11:25 AM
To: Elizabeth Holmes
Subject: times to talk

Elizabeth – I am so sorry about the schedule today and thanks for understanding! Looking at the calendar, I could either of the following times, whichever is best for you. I will be traveling Sunday and Monday and in meetings all day Tuesday. Look forward to catching up. Thanks.

Friday between 10a1pm

Wednesday 2-4pm

Thanks,
Bruce

Bruce Shepard, FACHE, Director, Health Business Development
Phone 479.204.6857 Fax 888.715.8940
bruce.shepard@wal-mart.com

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Assay Development Report
Theranos Systems Multiplexed Human IL-6, Human TNF-α, Human CRP (hs)

Contents

1. Introduction

The Theranos Assay System is a fully automated means for measuring concentrations of analytes (biomarkers, drugs) using immunoassay methodology. The system is comprised of instruments, single-use cartridges and a wireless communications link that conveys protocol information to the instruments from a Theranos Server and relays assay data to the Server for interpretation and distribution. Blood, plasma serum and control materials may be analyzed by the System. Calibration is performed at Theranos on a cartridge-lot-specific basis.

The System accepts a metered sample (25uL) from a proprietary sampling device or a pipette, dilutes it automatically to levels appropriate to each assay then executes an automated ELISA assay protocol. The protocol is selected from a set of released protocols available on the Theranos Server and identified by reading a bar code on each cartridge. The bar code is also linked to an assay lot-specific calibration algorithm. Assays are complete in about one hour.

Assays are typically grouped (multiplexed) in particular cartridges designed to monitor specific disease and therapeutic processes. For example, a cartridge designed to monitor acute and inflammatory processes measures IL-6, TNF-α and CRP. Customer is interested in use of the Theranos System and has sponsored a validation exercise at Theranos focused on the inflammatory marker cartridge.

In this exercise, many instruments (60) and three lots of cartridges were used.

2. Storage and Use

Theranos cartridges should be stored in the original unopened packaging in an upright position at 4°C. Theranos instruments require no user maintenance or calibration. User prompts are provided on a screen which is part of the instrument.

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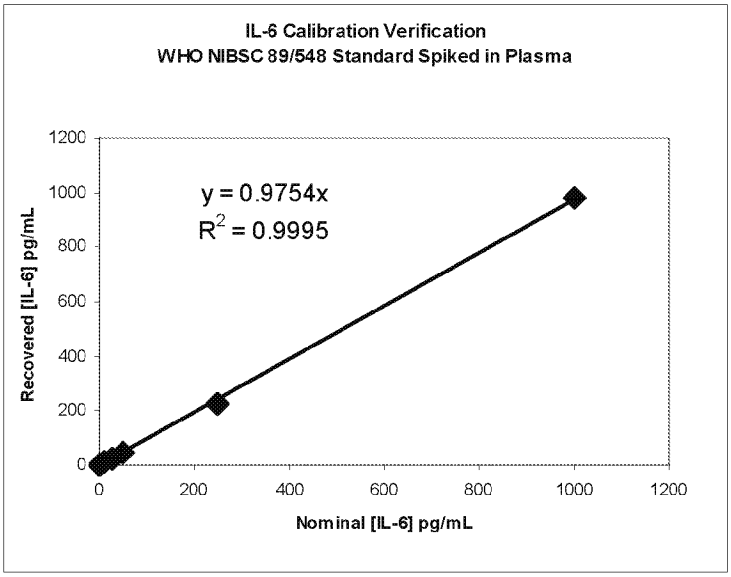
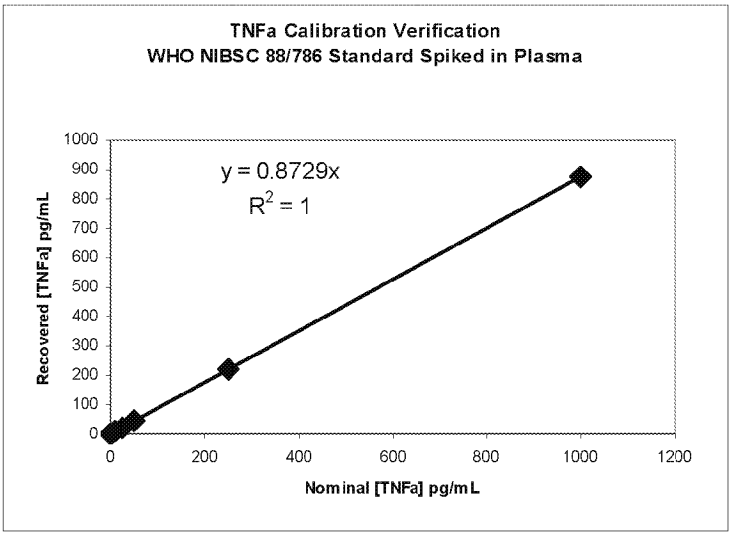
3. Calibration

IL-6 and TNF-α assay calibration utilize recombinant analytes expressed in human-cell lines as calibration materials. These are reportedly more stable than recombinant analytes made in bacteria and more similar to the naturally occurring analytes. The CRP assay is calibrated with a human plasma-derived analyte. Theranos Systems assays recognize "natural", recombinant, and human-cell line expressed recombinant forms of IL-6 and TNF-α. Each lot of Theranos Cartridges is individually calibrated, the calibration equation is linked to the cartridge barcode and results are automatically computed on the Theranos data server. For this validation study, three cartridge lots were produced and calibrated.

NIBSC WHO Verification of Calibration

Exemplary assay responses are shown in Appendix A. Calibrations for IL-6, TNF-α and CRP were verified by testing the recovery of the current National Institute for Biological Standards and Control (NIBSC) World Health Organization (WHO) Reference Standards. The current WHO standard for IL-6 is NIBSC code 89/548 (recombinant protein produced in CHO cells with post translational modifications), for TNF-α NIBSC code 88/786 (a natural human protein derived from human BALL-1 cells), and for CRP NIBSC code 85/506 from human plasma. Spike recovery of all three WHO standards were within acceptable limits across the assay ranges as shown in the figures and tables below. Note that for the TNF- α assay we found low recovery (about 30%) of the WHO standard in a reference kit (R&D Systems Quantikine HS catalogue # HSTA00D, data shown in Appendix B). Therefore comparisons of sensitivity and slopes of assay correlations of results of the Theranos System with those of R&D Systems kits will show different results due to their respective calibrations. For example, the R&D Systems Assay would report a TNF-α value of 4 pg/mL when the Theranos Assay reports 12 pg/mL. If desired by a customer the Theranos System can be configured (in calibration algorithms) to provide results matching those of R&D Systems assays (or those of other predicate assay). It is our intention however to continue to perform primary calibration of Theranos assays using International Standard materials whenever possible since predicate assays not so calibrated may be subject to lot-to-lot variation in calibration.


IL-6 Calibration Verification
WHO NIBSC 89/548 Standard Spiked in Plasma
y = 0.9754x
R2 = 0.9995
Recovered [IL-6] pg/mL
Nominal [IL-6] pg/mL
0
200
400
600
800
1000
1200


TNFa Calibration Verification
WHO NIBSC 88/786 Standard Spiked in Plasma
y = 0.8729x
R2 = 1
Recovered [TNFa] pg/mL
Nominal [TNFa] pg/mL
0
100
200
300
400
500
600
700
800
900
1000
1200

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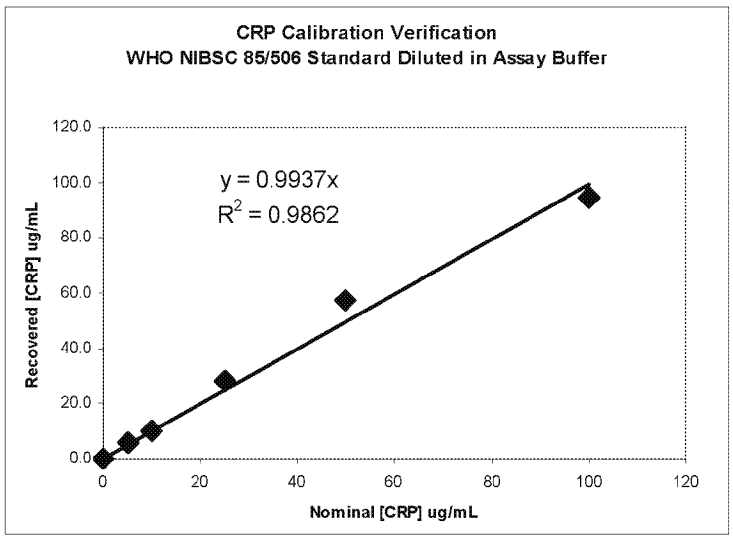

Theranos Systems Recovery of IL-6 (NIBSC code 89/548) Spiked in Plasma n=3 cartridges, 3 instruments per level					
[IL-6] IU/mL	**[IL-6] pg/ml**	**Recovered [IL-6] pg/mL**	**CV %**	**Minus Endogenous**	**% Recovery**
100	1000	981.1	11	980.1	98
25	250	227.1	16	226.2	90
5	50	45.2	10	44.2	88
3	25	21.5	8	20.5	82
1	10	10.5	9	9.5	95
0	0	1.0	47	0.0	N/A

Theranos Systems Recovery of TNF-α (NIBSC code 88/786) Spiked in Plasma n=3 cartridges, 3 instruments per level					
[TNFa] IU/mL	**[TNFa] pg/mL**	**Recovered [TNF-α] pg/mL**	**CV %**	**Minus Endogenous**	**% Recovery**
46.5	1000	873.4	3	873.0	89
11.6	250	218.7	3	218.3	96
2.3	50	44.0	10	43.5	96
1.2	25	20.9	22	20.4	95
0.5	10	10.9	19	10.5	100
0	0	0.4	14	0.0	N/A

Theranos Systems Recovery of CRP (NIBSC code 85/506) in Assay Buffer n=3 cartridges, 3 instruments per level				
[CRP] IU/mL	**[CRP] ug/ml**	**Recovered [CRP] ug/mL**	**CV %**	**% Recovery**
98	100	94.6	2	95
49	50	57.4	18	115
24.5	25	28.1	15	113
10	10	10.2	14	102
4.9	5	5.7	20	114

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0	0	0.0	30	N/A

4. Range

Reportable ranges based on calibration to WHO standards determined for these assays are:

Assay	Low	High
IL-6	2 pg/mL	1000 pg/mL
TNF-α	4[1] pg/mL	1000 pg/mL
CRP	0.05 ug/mL	100 ug/mL

As shown below, all three tested lots support these ranges[2].

5. Quantitation Limits

Assay calibrations and determination of Lower Limit of Quantitation (LLOQ) and Upper Limit of Quantitation (ULOQ) were performed and analyzed by proprietary software. Assay responses were fitted by a four-parameter equation and LLOQ and ULOQ determined according to FDA criteria. Calibrators were run in triplicate on three days (consecutive or non-consecutive) on 36 instruments for a total of nine cartridges per level, at 12 levels.

Summary of Calibration Analysis for three Cartridge Lots

Lot 2455142005	**IL-6**	**TNF-α**	**CRP**
LLOQ	1.3 pg/mL	6.3 pg/mL	0.05 ug/mL
ULOQ	1000 pg/mL	1000 pg/mL	150 ug/mL
Lot 2455146006	**IL-6**	**TNF-α**	**CRP**
LLOQ	1.3 pg/mL	6.3 pg/mL	0.05 ug/mL
ULOQ	1000 pg/mL	1000 pg/mL	150 ug/mL
Lot 2455156002	**IL-6**	**TNF-α**	**CRP**
LLOQ	2.3 pg/mL	6.3 pg/mL	0.05 ug/mL
ULOQ	1000 pg/mL	1000 pg/mL	150 ug/mL

Limits of detection (LOD)

The range in the Limits of detection calculated as 2*Signal SD/Slope of dose response (□signal/□conc) are reported for the three lots of Theranos cartridges. Comparison data are also given for R&D Systems assays Minimum Detectable Dose "MDD" (which is equivalent to LOD). In addition to the calibration issue for the R&D Systems TNF-α assay discussed above which gives a four-fold lower limit for R&D Systems, we believe the calculation of MDD performed by R&D Systems may be compromised (falsely low) by the inability of any known

[1] Equivalent to 1 pg/mL in the R&D Systems assay calibrated using R&D Systems calibrators

[2] The lower limit of the reportable range of the TNF-α assay has been extended below the LLOQ so as not to restrict the reportable range too much. The LLOQ is higher than anticipated due to unexpectedly high imprecision of the assay in the cartridge lots used for validation compared with other cartridge lots used in pre-clinical work. We are presently investigating the root cause of this imprecision.

spectrometer to report optical density to the required precision needed to support the calculated values.

The CRP MDD reported by R&D Systems is highly misleading since it represents the concentration in the assay rather than in the sample (which "must be diluted" according to their package insert prior to assay). Note that the Theranos assay uses a sample which is diluted 5000-fold. If we compare the actual sensitivity *in the assay medium* the Theranos value would be about 0.006 ng/mL.

Assay System	IL-6 (pg/mL)	TNF-α(pg/mL)	CRP (ng/mL)
Theranos	0.9 – 1.5	3.7 – 5.2	28 - 31
R&D Systems	0.02 – 0.11	0.04 – 0.19	0.005 – 0.22
R&D Systems[3]		0.16 – 0.76	

6. Precision and Accuracy

Plasma with low endogenous analyte levels was spiked with three levels of the analytes were measured in 16 cartridges per level on 48 instruments. Recovery of the spiked analyte was good. Imprecision (% CV) ranged from 10 - 25 %. Note that the imprecision cited includes both instrument-instrument and cartridge-cartridge variance.

Spiked Plasma Samples (n=16 cartridges, n=48 instruments)

Nominal [IL-6] pg/mL	**Recovered [IL-6] pg/mL**	**StDev**	**CV %**	**% Recovery**
800.3	806.9	79.8	9.9	101
50.3	50.5	4.7	9.2	100
5.3	5.1	0.8	15.5	96
Nominal [TNFa] pg/mL	**Recovered [TNFa] pg/mL**	**StDev**	**CV %**	**% Recovery**
500.3	418.9	39.6	9.5	84
50.3	42.7	5.1	12.0	85
12.3	12.9	3.2	24.6	105
Nominal [CRP] ug/mL	**Recovered [CRP] ug/mL**	**StDev**	**CV %**	**% Recovery**
50.1	50.4	10.0	19.9	101
1.6	1.6	0.3	16.8	97
0.1	0.1	0.0	20.6	103

7. Specificity

Assays were tested for cross reactivity and interference by the factors listed below, at high, mid and low analyte levels. Potential cross-reactants were selected based on package inserts of recognized predicate methods and added at levels deemed to be higher than those likely to be found in clinical samples. No significant cross reactivity or interference was observed for any of the assays by any of the tested factors at all analyte levels tested.

[3] Recalculated to reflect calibration to WHO standard material

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IL-6 Assay Specificity Test in Spiked Plasma (n=3 cartridges, 3 instruments per level)					
Substance	**[Test Substance] ng/mL**	**Target [IL-6] pg/mL**	**Recovered [IL-6] pg/mL**	**CV %**	**% Recovery**
Control	0	1000.3	1100.3	7.8	110
	0	90.3	95.8	16.6	106
	0	8.3	9.4	4.8	113
IL-1α	10	1000.3	939.2	2.9	94
	10	90.3	97.0	15.7	107
	10	8.3	9.0	6.9	108
IL-2	10	1000.3	1047.7	1.7	105
	10	90.3	86.7	9.4	96
	10	8.3	8.7	22.3	105
IL-3	10	1000.3	950.0	12.7	95
	10	90.3	91.9	4.6	102
	10	8.3	7.9	4.4	95
IL-4	10	1000.3	908.0	10.9	91
	10	90.3	79.9	16.7	88
	10	8.3	8.1	18.1	97
IL-6 sR	50	1000.3	914.9	18.0	91
	50	90.3	81.2	1.3	90
	50	8.3	8.0	29.0	96
IL-7	10	1000.3	895.0	10.0	89
	10	90.3	78.1	9.1	87
	10	8.3	8.2	9.4	99
IL-8	10	1000.3	927.8	9.7	93
	10	90.3	82.3	17.1	91
	10	8.3	8.4	17.6	101
IL-11	10	1000.3	897.5	12.5	90
	10	90.3	90.3	6.1	100
	10	8.3	7.9	2.2	95
IL-12	10	1000.3	837.6	8.4	84
	10	90.3	85.8	14.7	95
	10	8.3	6.8	18.1	82
CNTF	10	1000.3	900.6	8.4	90
	10	90.3	95.3	5.8	106
	10	8.3	8.9	22.4	107
G-CSF	10	1000.3	925.0	18.7	92
	10	90.3	90.2	12.8	100
	10	8.3	9.7	6.9	117
sgp130	1000	1000.3	895.5	17.0	90
	1000	90.3	88.6	2.0	98
	1000	8.3	9.4	3.2	114
LIF R	50	1000.3	895.2	2.8	89
	50	90.3	78.5	16.5	87
	50	8.3	8.9	19.8	107
OSM	10	1000.3	945.4	9.5	95
	10	90.3	77.1	10.0	85

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IL-6 Assay Specificity Test in Spiked Plasma (n=3 cartridges, 3 instruments per level)					
Substance	**[Test Substance] ng/mL**	**Target [IL-6] pg/mL**	**Recovered [IL-6] pg/mL**	**CV %**	**% Recovery**
	10	8.3	6.9	16.8	83
TNF-β	10	1000.3	919.6	8.6	92
	10	90.3	83.3	15.8	92
	10	8.3	9.4	7.8	113
IL-1β	10	1000.3	901.2	8.1	90
	10	90.3	85.7	17.6	95
	10	8.3	7.5	10.5	90
sTNF RI	10	1000.3	1025.2	9.2	102
	10	90.3	83.4	11.4	92
	10	8.3	9.4	16.5	114
sTNF RII	10	1000.3	963.3	13.8	96
	10	90.3	90.7	10.2	100
	10	8.3	9.3	21.0	112

TNF-α Assay Specificity Test in Spiked Plasma (n=3 cartridges, 3 instruments per level)					
Substance	**[Test Substance] ng/mL**	**Target [TNFa] pg/mL**	**Recovered [TNFa] pg/mL**	**CV %**	**% Recovery**
Control	0	900.3	883.7	4.1	98
	0	90.3	85.4	4.1	95
	0	8.3	8.3	40.4	100
IL-1α	10	900.3	849.1	5.5	94
	10	90.3	89.6	12.7	99
	10	8.3	8.8	16.0	106
IL-2	10	900.3	855.2	23.5	95
	10	90.3	90.8	7.9	101
	10	8.3	9.6	18.5	116
IL-3	10	900.3	836.5	23.5	93
	10	90.3	74.3	5.4	82
	10	8.3	8.2	29.2	98
IL-4	10	900.3	884.6	6.9	98
	10	90.3	89.5	8.5	99
	10	8.3	7.0	49.3	84
IL-6 sR	50	900.3	874.0	23.5	97
	50	90.3	77.8	13.8	86
	50	8.3	8.6	34.8	103
IL-7	10	900.3	871.9	6.3	97
	10	90.3	82.8	37.1	92
	10	8.3	7.6	22.9	91
IL-8	10	900.3	774.4	1.8	86
	10	90.3	83.4	13.5	92
	10	8.3	7.9	12.6	95
IL-11	10	900.3	901.8	1.5	100
	10	90.3	90.7	19.6	100
	10	8.3	9.3	36.8	112
IL-12	10	900.3	770.9	7.3	86

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TNF-α Assay Specificity Test in Spiked Plasma (n=3 cartridges, 3 instruments per level)					
Substance	**[Test Substance] ng/mL**	**Target [TNFa] pg/mL**	**Recovered [TNFa] pg/mL**	**CV %**	**% Recovery**
	10	90.3	77.4	15.8	86
	10	8.3	7.9	56.7	96
CNTF	10	900.3	920.1	6.0	102
	10	90.3	82.5	9.7	91
	10	8.3	8.7	18.9	105
G-CSF	10	900.3	1052.6	3.7	117
	10	90.3	95.6	20.7	106
	10	8.3	9.1	9.6	110
sgp130	1000	900.3	891.3	16.8	99
	1000	90.3	93.8	9.1	104
	1000	8.3	10.1	25.1	122
LIF R	50	900.3	781.5	20.7	87
	50	90.3	87.3	15.2	97
	50	8.3	9.1	12.1	110
OSM	10	900.3	862.1	10.6	96
	10	90.3	85.2	23.8	94
	10	8.3	7.4	54.1	89
TNF-β	10	900.3	804.0	24.7	89
	10	90.3	90.7	16.4	100
	10	8.3	7.7	32.3	92
IL-1β	10	900.3	900.0	17.3	100
	10	90.3	83.1	16.6	92
	10	8.3	8.3	33.1	101
sTNF RI	10	900.3	833.0	21.8	93
	10	90.3	86.4	19.5	96
	10	8.3	6.7	21.6	80
sTNF RII	10	900.3	801.3	8.9	89
	10	90.3	93.6	3.0	104
	10	8.3	8.2	14.2	99

CRP Assay Specificity Test in Assay Buffer (n=3 cartridges, 3 instruments per level)					
Substance	**[Test Substance] ng/mL**	**Target [CRP] ug/ml**	**Recovered [CRP] ug/ml**	**CV %**	**% Recovery**
Control	0	50	53.0	16	106
	0	10	8.1	34	81
	0	0.75	0.7	13	91
Pentraxin-2/SAP	30	50	49.2	19	98
	30	10	8.9	9	89
	30	0.75	0.8	4	102
Pentraxin-3/TSG-14	10	50	40.6	7	81
	10	10	8.2	14	82
	10	0.75	0.7	5	100

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8. Linearity

A plasma sample with low endogenous analyte levels was spiked with known levels of IL-6, TNF-α, and CRP then diluted serially with the unspiked plasma. All assays showed an appropriate linear dilution response across the dilution range (500 – 2000-fold). Data are tabulated and graphed below.

Dilution Linearity in Plasma, Multiplexed Assays (n=3 cartridges, 3 instruments per level)

IL-6				
Spiked [IL-6] pg/mL	**[Expected] pg/ml**	**[Recovered] pg/mL**	**CV %**	**% Recovery**
950	950.5	958.1	7	101
	475.5	480.9	11	101
	238.0	256.1	18	108
	119.2	143.9	25	121
	59.8	62.3	3	104
	30.1	28.3	23	94
	15.3	13.3	34	87
	0.5	0.5	88	100

TNF-α				
Spiked [TNFa] pg/mL	**[Expected] pg/ml**	**[Recovered] pg/mL**	**CV %**	**% Recovery**
900	902.7	899.2	11	100
	452.7	461.5	9	102
	227.7	194.6	6	85
	115.2	105.0	11	91
	59.0	56.1	2	95
	30.9	30.6	4	99
	16.8	14.9	26	89
	2.7	2.7	14	100

CRP				
Spiked [CRP] ug/mL	**[Expected] ug/ml**	**[Recovered] ug/mL**	**CV %**	**% Recovery**
75	75.1	82.8	34	110
	37.6	35.0	0	93
	18.8	14.7	10	78
	9.5	9.1	12	96
	4.8	4.1	8	85
	2.4	2.4	7	98
	1.3	1.3	15	102
	0.1	0.1	29	100

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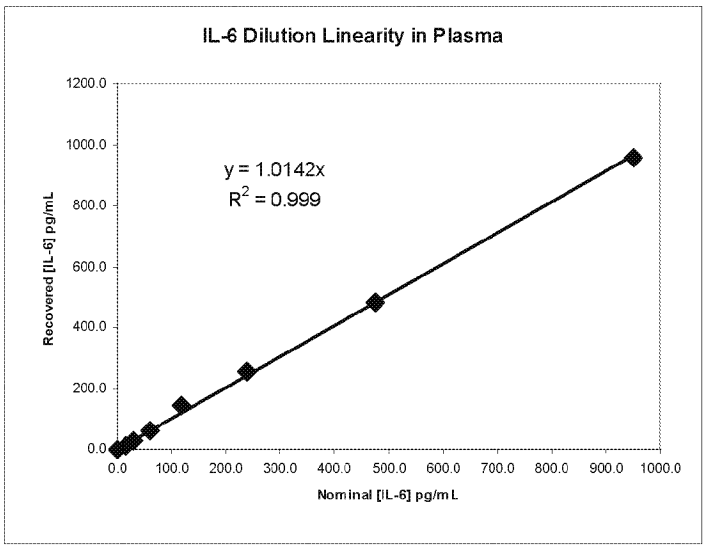

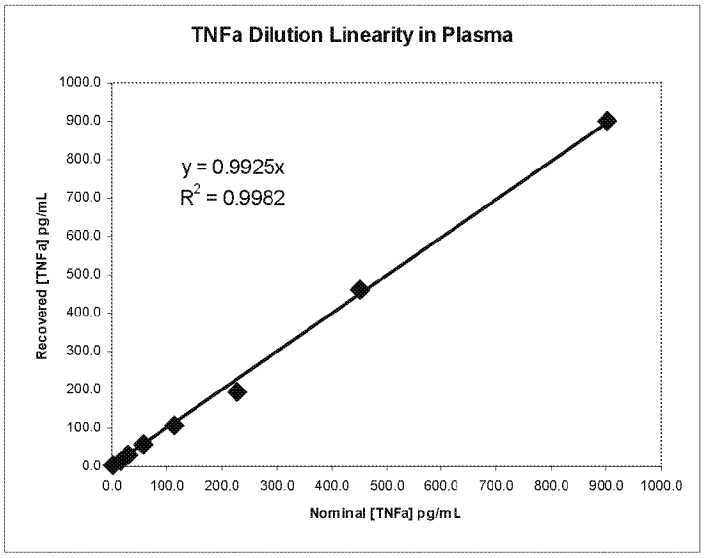

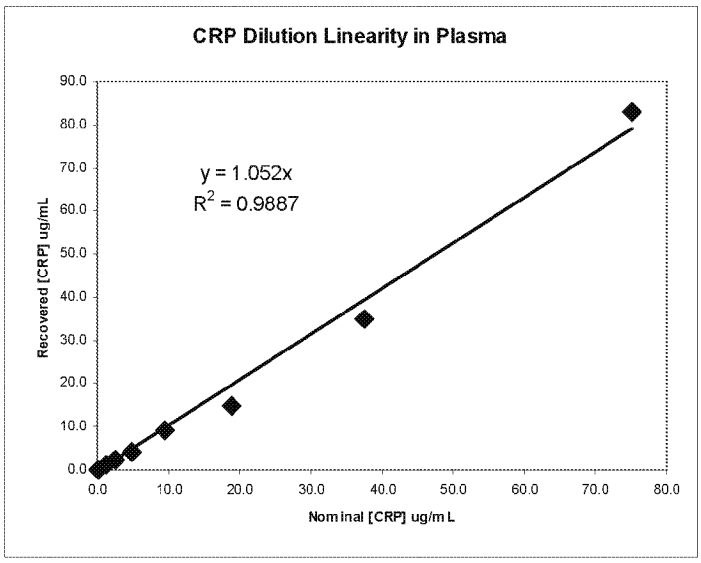

9. Matrix Effects

Plasma or serum containing various potentially interfering factors or substances were spiked with known levels of analyte and the resulting recovery of the spiked analyte calculated after correction for endogenous analyte. None of the assays showed interference from icteric, hemolyzed, lipemic, or rheumatoid factor-positive samples as shown in the tables below

NORMAL SERUM Sample: PromedDx 10739123 (n=3 cartridges, 3 instruments per level)

Spiked [IL-6] pg/mL	Recovered [IL-6] pg/mL	CV %	Minus Endogenous	% Recovery
1000	1019.1	14	1015.82	102
250	224.9	4	221.58	89
50	47.7	14	44.42	89
25	25.3	6	22.01	88
10	12.6	9	9.29	93
0	3.3	43	0.00	
Spiked [TNFa] pg/mL	**Recovered [TNFa] pg/mL**	**CV %**	**Minus Endogenous**	**% Recovery**
1000	1019.1	14	1014.7	101
250	224.9	4	220.5	88
50	47.7	14	43.3	87
25	25.3	6	20.9	84
10	12.6	9	8.2	82
0	4.4	60	0.0	
Spiked [CRP] ug/mL	**Recovered [CRP] ug/mL**	**CV %**	**Minus Endogenous**	**% Recovery**
100	107.4	11	107.3	107
50	49.3	13	49.3	99
25	25.0	23	24.9	100
10	9.6	41	9.5	95
5	5.9	17	5.8	116
0	0.1	12	0.0	

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LIPEMIC SERUM Sample: Vital Products SFB8315 (n=3 cartridges, 3 instruments per level)

Spiked [IL-6] pg/mL	Recovered [IL-6] pg/mL	CV %	Minus Endogenous	% Recovery
1000	872.5	15	868.8	87
250	214.1	4	210.4	84
50	47.8	15	44.1	88
25	24.5	6	20.8	83
10	14.4	19	10.7	107
0	3.7	12	0.0	
Spiked [TNFa] pg/mL	**Recovered [TNFa] pg/mL**	**CV %**	**Minus Endogenous**	**% Recovery**
1000	965.0	17	962.8	96
250	230.8	15	228.6	91
50	56.6	40	54.4	109
25	25.4	13	23.2	93
10	14.8	14	12.6	126
0	2.2	32	0.0	
Spiked [CRP] ug/mL	**Recovered [CRP] ug/mL**	**CV %**	**Minus Endogenous**	**% Recovery**
100	119.4	36	119.1	119
50	54.2	40	53.9	108
25	24.4	25	24.1	96
10	10.4	9	10.1	101
5	5.8	15	5.6	111
0	0.2	12	0.0	

HEMOLYZED PLASMA Sample: Stanford W070509118560 (n=3 cartridges, 3 instruments per level)

Spiked [IL-6] pg/mL	Recovered [IL-6] pg/mL	CV %	Minus Endogenous	% Recovery
1000	1010.9	10	1010.0	101
250	274.6	13	273.7	109
50	51.6	2	50.7	101
25	26.8	11	25.9	104
10	10.5	12	9.6	96
0	0.9	41	0.0	
Spiked [TNFa] pg/mL	**Recovered [TNFa] pg/mL**	**CV %**	**Minus Endogenous**	**% Recovery**
1000	898.7	14	895.1	90
250	223.5	12	219.9	88
50	44.2	11	40.6	81
25	27.7	23	24.1	96
10	12.0	23	8.4	84
0	3.6	14	0.0	
Spiked [CRP] ug/mL	**Recovered [CRP] ug/mL**	**CV %**	**Minus Endogenous**	**% Recovery**
100	119.6	10	119.5	119
50	54.0	10	53.9	108
25	22.5	14	22.4	90
10	11.6	3	11.5	115
5	5.6	11	5.5	110
0	0.1	4	0.0	

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ICTERIC SERUM Sample: PromedDx 10739123 (n=3 cartridges, 3 instruments per level)

Spiked [IL-6] pg/mL	Recovered [IL-6] pg/mL	CV %	Minus Endogenous	% Recovery
1000	986.0	9	983.4	98
250	282.4	12	279.7	112
50	55.8	10	53.2	106
25	28.1	7	25.4	102
10	11.8	16	9.2	92
0	2.6	53	0.0	
Spiked [TNFa] pg/mL	**Recovered [TNFa] pg/mL**	**CV %**	**Minus Endogenous**	**% Recovery**
1000	969.8	5	967.4	97
250	219.6	22	217.2	87
50	45.0	11	42.6	85
25	24.5	5	22.1	88
10	10.6	22	8.2	82
0	2.4	17	0.0	
Spiked [CRP] ug/mL	**Recovered [CRP] ug/mL**	**CV %**	**Minus Endogenous**	**% Recovery**
100	109.5	8	108.4	108
50	41.7	80	40.6	81
25	29.6	14	28.4	114
10	10.1	11	9.0	90
5	6.4	19	5.3	106
0	1.1	3	0.0	

RHEUMATOID FACTOR POSITIVE SERUM Sample: Vital Products SFB7884
(n=3 cartridges, 3 instruments per level)

Spiked [IL-6] pg/mL	Recovered [IL-6] pg/mL	CV %	Minus Endogenous	% Recovery
1000	1118.0	10	1097.9	110
250	286.9	9	266.7	107
50	77.7	13	57.6	115
25	46.3	12	26.2	105
10	30.4	6	10.2	102
0	20.1	6	0.0	
Spiked [TNFa] pg/mL	**Recovered [TNFa] pg/mL**	**CV %**	**Minus Endogenous**	**% Recovery**
1000	1116.4	11	1112.3	111
250	228.9	5	224.8	90
50	48.0	13	43.9	88
25	24.2	13	20.1	80
10	14.0	20	9.9	99
0	4.1	27	0.0	
Spiked [CRP] ug/mL	**Recovered [CRP] ug/mL**	**CV %**	**Minus Endogenous**	**% Recovery**
100	110.9	18	105.8	106
50	49.1	17	44.0	88
25	34.2	29	29.0	116
10	15.5	9	10.3	103
5	10.9	11	5.7	114
0	5.2	28	0.0	

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10. Stability

The stability of component reagents for the present assays has been studied individually in lots made previous to the present study. The capture surfaces were stable for over 12 months, and the detection conjugates for at least six months. Stability of the integrated cartridges used for this validation report stored at 4C is being monitored and an updated report will include this data. Cartridges are initially assigned an expiry date of three months post manufacture.

Conclusions:

The Theranos IL-6, TNF-α, CRP assay multiplex has been shown to give accurate and precise results for three independently calibrated cartridge lots and all the many instruments used. Assay calibration has been established using WHO or other standard materials. Lower and upper levels of quantitation have been established. The assays are specific for their respective analytes when tested against potential cross reactants and are not interfered with by agents that may cause problems in immunoassays. Dilution linearity is satisfactory for all the assays. Assay cartridge stability studies are underway.

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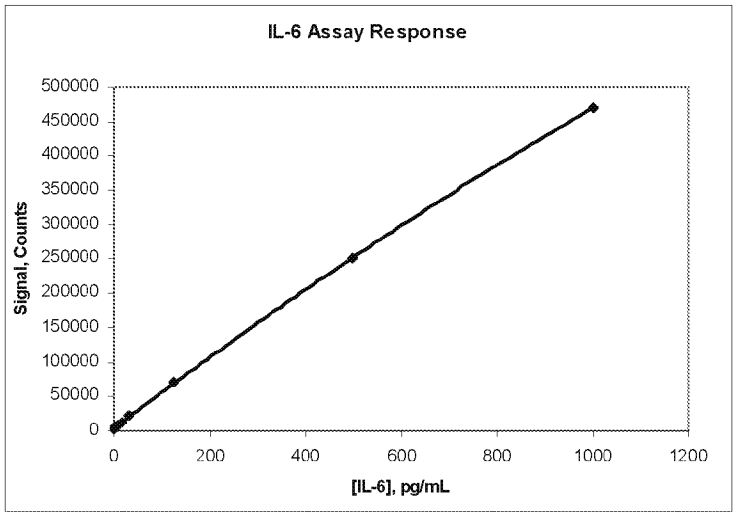
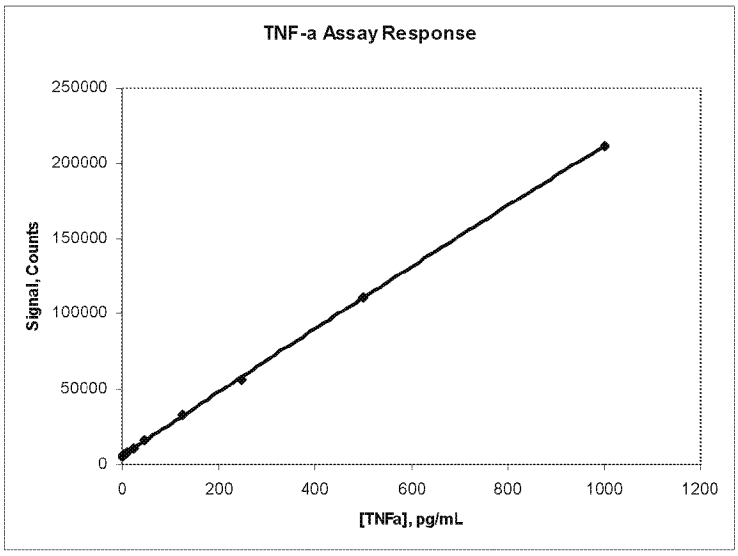
Appendix A





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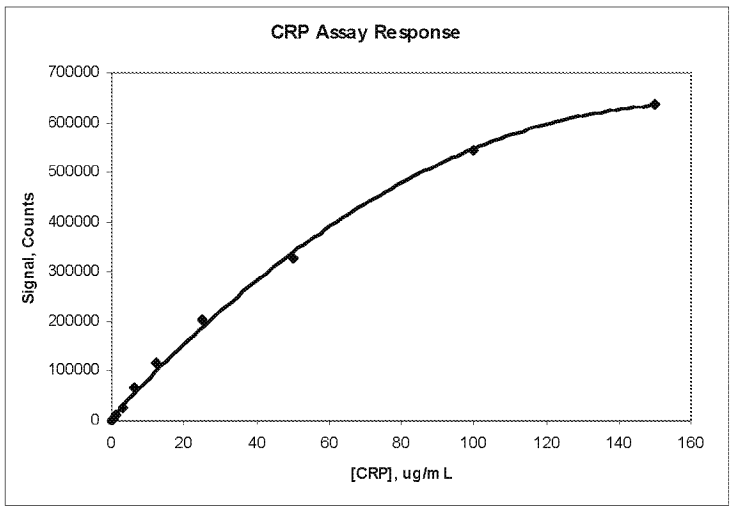

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Appendix B

Comparison of Theranos Systems TNFa Calibration to Other Available Commercial Methods

Plasma samples were spiked with WHO TNF-a Standard (NIBSC code 88/786) and run in Theranos Systems and in R&D Quantikine High Sensitivity Human TNF-α ELISA (catalogue # HSTA00D). The results are shown below.

THERANOS SYSTEMS Recovery of TNFa WHO Standard Spiked in Plasma

Nominal Spike		1pg/mL = 0.0465 IU/mL			
[TNFa] IU/ml	**[TNFa] pg/ml**	**Calc. pg/mL**	**Minus Endogenous**	**Calc. IU/mL**	**% Recovery**
0	0	5.2	0.0		
0.1	2.5	8.1	2.9	0.1	118
0.2	5	11.5	6.3	0.3	126
0.5	10	14.9	9.7	0.5	97
1.2	25	35.9	30.8	1.4	123
2.3	50	57.6	52.4	2.4	105
11.6	250	217.6	212.5	9.9	85
46.5	1000	1120.6	1115.4	51.9	112

R&D QUANTIKINE HS ELISA Recovery of TNFa WHO Standard Spiked in Plasma

Nominal Spike		1pg/mL = 0.0465 IU/mL			
[TNFa] IU/ml	**[TNFa] pg/ml**	**Calc. pg/mL**	**Minus Endogenous**	**Calc. IU/mL**	**% Recovery**
0	0	0.2	0.0		
0.1	2.5	1.0	0.8	0.04	32
0.2	5	1.8	1.6	0.07	32
0.5	10	3.2	3.0	0.14	30
1.2	25	7.3	7.1	0.3	28
2.3	50	15.0	14.8	0.7	30
11.6	250	83.6	83.4	3.9	33
46.5	1000	308.0	307.7	14.3	31